

Horizon Pharma plc  
Form 10-Q  
November 06, 2014  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(MARK ONE)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2014

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 001-35238

**HORIZON PHARMA PUBLIC LIMITED COMPANY**

(Exact name of registrant as specified in its charter)

**Ireland**  
(State or other jurisdiction  
of incorporation or organization)

**Not Applicable**  
(I.R.S. Employer  
Identification No.)

**Adelaide Chambers**

**Peter Street, Dublin 8, Ireland**  
(Address of principal executive offices)

**Not Applicable**  
(Zip Code)

**011 353 1 649 8521**

(Registrant's telephone number, including area code)

**Not applicable**

(Former name, former address and former fiscal year, if changed since last report)

## Edgar Filing: Horizon Pharma plc - Form 10-Q

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act:

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Number of registrant's ordinary shares, nominal value \$0.0001, outstanding as of November 3, 2014: 118,852,790.

**Table of Contents**

**HORIZON PHARMA PLC**

**INDEX**

	<b>Page No.</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
Item 1. <u>Financial Statements</u>	1
<u>Condensed Consolidated Balance Sheets as of September 30, 2014 and as of December 31, 2013 (Unaudited)</u>	1
<u>Condensed Consolidated Statements of Comprehensive Income (Loss) for the Three and Nine Months Ended September 30, 2014 and 2013 (Unaudited)</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2014 and 2013 (Unaudited)</u>	3
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	4
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	36
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	49
Item 4. <u>Controls and Procedures</u>	50
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	51
Item 1A. <u>Risk Factors</u>	52
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	85
Item 6. <u>Exhibits</u>	87
<u>Signatures</u>	88

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements**

**HORIZON PHARMA PLC**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(UNAUDITED)

(In thousands, except share data)

	September 30, 2014	December 31, 2013
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 248,781	\$ 80,480
Restricted cash	738	738
Accounts receivable, net	80,022	15,958
Inventories, net	23,848	8,701
Prepaid expenses and other current assets	7,378	4,888
Total current assets	360,767	110,765
Property and equipment, net	4,656	3,780
Other intangible assets, net	131,870	66,274
Developed technology, net	612,068	64,820
Other assets	15,534	6,957
<b>TOTAL ASSETS</b>	<b>\$ 1,124,895</b>	<b>\$ 252,596</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Convertible debt, net	\$ 116,799	\$
Accounts payable	22,197	9,921
Accrued trade discounts and rebates	70,501	8,123
Accrued expenses	39,431	15,926
Accrued royalties - current portion	25,876	8,010
Deferred revenues - current portion	1,350	1,330
Total current liabilities	276,154	43,310
<b>LONG-TERM LIABILITIES:</b>		
Convertible debt, net of current		110,762
Long term debt	297,022	
Derivative liability		109,410
Accrued royalties, net of current	53,368	24,982
Deferred revenues, net of current	8,629	9,686
Deferred tax liabilities, net	4,083	3,362
Other long term liabilities	154	166
Total long-term liabilities	363,256	258,368

**COMMITMENTS AND CONTINGENCIES**

**SHAREHOLDERS EQUITY:**

Ordinary shares, \$0.0001 nominal value; 300,000,000 shares authorized; 106,151,328 and 66,097,417 shares issued at September 30, 2014 and December 31, 2013, respectively, and 105,766,962 and 66,097,417 shares outstanding at September 30, 2014 and December 31, 2013, respectively	11	7
Treasury stock, 384,366 ordinary shares at September 30, 2014	(4,585)	
Additional paid-in capital	1,182,327	410,430
Accumulated other comprehensive loss	(3,196)	(2,403)
Accumulated deficit	(689,072)	(457,116)
<b>Total shareholders equity (deficit)</b>	<b>485,485</b>	<b>(49,082)</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS EQUITY</b>	<b>\$ 1,124,895</b>	<b>\$ 252,596</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Table of Contents****HORIZON PHARMA PLC****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS****(UNAUDITED)****(In thousands, except share and per share data)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>REVENUES:</b>				
Net sales	\$ 75,126	\$ 24,112	\$ 193,114	\$ 43,936
Cost of goods sold	13,644	3,207	46,073	9,370
Gross profit	61,482	20,905	147,041	34,566
<b>OPERATING EXPENSES:</b>				
Research and development	4,223	2,154	10,601	7,185
Sales and marketing	31,111	15,621	86,932	48,475
General and administrative	38,109	5,874	66,982	15,998
Total operating expenses	73,443	23,649	164,515	71,658
Operating loss	(11,961)	(2,744)	(17,474)	(37,092)
<b>OTHER INCOME (EXPENSE), NET:</b>				
Interest expense, net	(5,194)	(3,601)	(13,608)	(10,646)
Foreign exchange (loss) gain	(2,754)	1,118	(3,076)	667
Loss on derivative fair value			(214,995)	
Bargain purchase gain	22,171		22,171	
Other, net	(3,241)		(8,241)	
Total other income (expense), net	10,982	(2,483)	(217,749)	(9,979)
Loss before (benefit) expense for income taxes	(979)	(5,227)	(235,223)	(47,071)
<b>BENEFIT (EXPENSE) FOR INCOME TAXES</b>	<b>(3,042)</b>	<b>265</b>	<b>(3,267)</b>	<b>(967)</b>
<b>NET INCOME (LOSS)</b>	<b>\$ 2,063</b>	<b>\$ (5,492)</b>	<b>\$ (231,956)</b>	<b>\$ (46,104)</b>
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:</b>				
Basic	78,392,971	64,645,677	73,109,603	63,168,797
Diluted	85,687,267	64,645,677	73,109,603	63,168,797
<b>NET INCOME (LOSS) PER SHARE:</b>				
Basic	\$ 0.03	\$ (0.08)	\$ (3.17)	\$ (0.73)
Diluted	\$ 0.02	\$ (0.08)	\$ (3.17)	\$ (0.73)
<b>OTHER COMPREHENSIVE INCOME (LOSS), NET OF TAX</b>				
Foreign currency translation adjustments	(654)	993	(793)	598
Other comprehensive (loss) income	(654)	993	(793)	598
<b>COMPREHENSIVE INCOME (LOSS)</b>	<b>\$ 1,409</b>	<b>\$ (4,499)</b>	<b>\$ (232,749)</b>	<b>\$ (45,506)</b>

## Edgar Filing: Horizon Pharma plc - Form 10-Q

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Table of Contents****HORIZON PHARMA PLC****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(UNAUDITED)****(In thousands)**

	<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (231,956)	\$ (46,104)
<b>Adjustments to reconcile net loss to net cash provided by (used in) operating activities:</b>		
Change in estimate of VIMOVO royalties	13,033	
Depreciation and intangible amortization expense	17,662	5,838
Share-based compensation	10,111	3,206
Royalty accretion	5,617	
Loss on derivative revaluation	214,995	
Bargain purchase gain	(22,171)	
Amortization of debt discount and deferred financing costs	7,087	3,043
Loss on asset disposal	11	
Paid in kind interest expense		2,228
Foreign exchange loss (gain)	3,076	(667)
Changes in operating assets and liabilities:		
Accounts receivable	(52,033)	(13,211)
Inventories	129	(1,626)
Prepaid expenses and other current assets	(2,091)	499
Accounts payable	10,555	(951)
Accrued trade discounts and rebates	46,113	6,206
Accrued expenses	796	(45)
Deferred revenues	(324)	(869)
Deferred tax liabilities	(3,278)	(988)
Other non-current assets and liabilities	138	332
Net cash provided by (used in) operating activities	17,470	(43,109)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Payment for acquisition, net of cash acquired	(179,220)	
Purchases of property and equipment	(1,837)	(643)
Net cash used in investing activities	(181,057)	(643)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from the issuance of debt, net of underwriting fees and issuance costs	286,966	
Proceeds from the issuance of ordinary shares in connection with warrant and stock option exercises	34,966	
Proceeds from the settlement of capped call transactions	9,385	
Proceeds from the issuance of ordinary shares under an ATM agreement, net of issuance costs		5,998
Proceeds from the issuance of ordinary shares through ESPP programs	649	213
Repayment of notes payable		(7,956)
Net cash provided by (used in) financing activities	331,966	(1,745)



Edgar Filing: Horizon Pharma plc - Form 10-Q

Effect of foreign exchange rate changes on cash	(78)	60
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>168,301</b>	<b>(45,437)</b>
<b>CASH AND CASH EQUIVALENTS, beginning of the year</b>	<b>80,480</b>	<b>104,087</b>
<b>CASH AND CASH EQUIVALENTS, end of the period</b>	<b>\$ 248,781</b>	<b>\$ 58,650</b>

**Supplemental cash flow information:**

Cash paid for interest	\$ 3,604	\$ 5,517
Cash paid for income taxes	29	35
Debt commitment fees	8,222	

See Note 4 for assets acquired and liabilities assumed from acquisition

The accompanying notes are an integral part of these condensed consolidated financial statements.

---

**Table of Contents**

**HORIZON PHARMA PLC**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(In thousands, except share and per share data)**

**NOTE 1 BASIS OF PRESENTATION**

On September 19, 2014, the businesses of Horizon Pharma, Inc. ( HPI ) and Vidara Therapeutics International Public Limited Company ( Vidara ) were combined in a merger transaction (the Merger ), accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with HPI treated as the acquiring company in the Merger for accounting purposes. As part of the Merger, a wholly-owned subsidiary of Vidara merged with and into HPI, with HPI surviving the Merger as a wholly-owned subsidiary of Vidara. Prior to the Merger, Vidara changed its name to Horizon Pharma plc ( New Horizon or the Company ). Upon the consummation of the Merger, the historical financial statements of HPI became the Company s historical financial statements. Accordingly, the historical financial statements of HPI are included in the comparative prior periods.

The unaudited condensed consolidated financial statements presented herein have been prepared in accordance with accounting principles generally accepted in the United States ( GAAP ) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, all adjustments, including normal recurring adjustments, considered necessary for a fair statement of the financial statements have been included. Operating results for the three and nine months ended September 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. The December 31, 2013 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by GAAP.

The unaudited condensed consolidated financial statements presented herein include the accounts of the Company and its wholly-owned subsidiaries. All inter-company transactions and balances have been eliminated. Additionally, certain reclassifications have been made to prior period financial statements to conform to the current period presentation.

During the second quarter of 2014, the Company changed its income statement presentation to present net sales rather than presenting gross sales minus sales discounts and allowances. The revised presentation has no effect on net sales, gross margin dollars, net income, cash flows, working capital or shareholders equity amounts previously reported, and will not affect such amounts in future periods.

During the first quarter of 2014, the Company recorded an out of period correction of \$1,578 resulting in a reduction to its wholesaler fees related to prior periods. This correction to wholesaler fees was recorded as an increase in net sales within the Company s condensed consolidated statements of comprehensive loss for the six months ended June 30, 2014. The Company has evaluated the impact of the reduction in wholesaler fees to prior reporting periods and has determined it was immaterial.

During the fourth quarter of 2013, the Company determined that there had been a misclassification of certain fees in its financial statements for the previously reported periods. Those financial statements classified wholesaler service fees as cost of goods sold. The Company determined that these fees should be classified as a reduction to net sales instead of an increase in cost of goods sold and has revised all identified prior period misclassifications in the periods in which they originated. The revision had no impact on the Company s reported gross profit, net loss or cash flows and was immaterial individually or in the aggregate, to any of the prior reporting periods. Amounts included within this Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2013 have been revised to reflect an adjustment of \$2,106 and \$3,707, respectively, from cost of goods sold to net sales. The revision reduced both net sales and cost of goods sold by these amounts.

**Business Overview**

The Company is a specialty biopharmaceutical company focused on improving patients lives by identifying, developing, acquiring and commercializing differentiated products that address unmet medical needs. The Company markets a portfolio of products in arthritis, inflammation and orphan diseases. The Company s U.S. marketed products are ACTIMMUNE® (interferon gamma-1b), DUEXIS® (ibuprofen/famotidine), RAYOS® (prednisone) delayed-release tablets and VIMOVO® (naproxen/esomeprazole). The Company developed DUEXIS and RAYOS/LODOTRA, acquired the U.S. rights to VIMOVO from AstraZeneca AB ( AstraZeneca ) in November 2013 and acquired the U.S. rights to ACTIMMUNE as a result of the Merger. The Company markets its products in the United States through a combined field sales force of approximately 310 representatives consisting of approximately 260 primary care sales representatives and 50 sales representatives in its specialty and orphan diseases business areas. The Company s strategy is to develop, acquire or in-license additional innovative medicines or acquire companies, such as the addition of ACTIMMUNE through the recently-completed Merger with Vidara and the acquisition of the U.S.

## Edgar Filing: Horizon Pharma plc - Form 10-Q

rights to PENNSAID® (diclofenac sodium topical solution) 2% w/w ( PENNSAID 2% ) from Nuvo Research Inc. ( Nuvo ), announced on October 17, 2014

## Table of Contents

The Company is a public limited company formed under the laws of Ireland. As a result of the Merger, the Company operates through a number of international and U.S. subsidiaries with principal business purposes to either hold intellectual property assets, perform research and development or manufacturing operations, serve as distributors of the Company's products, or provide services and financial support to the Company. The Company's international operations are conducted primarily through Horizon Pharma Ireland Limited which is responsible for manufacturing ACTIMMUNE and other products the Company may potentially acquire, and Horizon Pharma AG, a company organized under the laws of Switzerland, along with its wholly-owned subsidiary Horizon Pharma GmbH, a company organized under the laws of Germany, together which are responsible for manufacturing RAYOS/LODOTRA, and for international sales of LODOTRA. The Company's U.S. operations are conducted primarily through Horizon Pharma USA, Inc. which is responsible for research and development and manufacturing of DUEXIS and VIMOVO, and distribution in the U.S. market of DUEXIS, VIMOVO and RAYOS, and other products the Company may potentially acquire, such as the recently acquired PENNSAID 2%, as well as through HZNP USA Inc. which is responsible for distribution of ACTIMMUNE in the United States. Unless otherwise indicated or the context otherwise requires, references to the Company, New Horizon, we, us and our refer to Horizon Pharma plc and its consolidated subsidiaries, including its predecessor, HPI. All references to Vidara or the acquired company are references to Horizon Pharma plc (f/k/a Vidara Therapeutics International Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Merger on September 19, 2014. The disclosures in this report relating to the pre-Merger business of Horizon Pharma plc, unless noted as being the business of Vidara prior to the Merger, pertain to the business of HPI prior to the Merger.

On April 23, 2011, the U.S. Food and Drug Administration (FDA) approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis (RA), osteoarthritis (OA) and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. The Company began detailing DUEXIS to physicians in December 2011. In June 2012, the Company licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products.

The Company's second approved product in the United States, RAYOS, known as LODOTRA outside the United States, is a proprietary delayed-release formulation of low-dose prednisone, first approved in Europe in March 2009, for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatica (PMR), psoriatic arthritis, ankylosing spondylitis (AS), asthma and chronic obstructive pulmonary disease and a number of other conditions. The Company is focusing its promotion of RAYOS in the United States on rheumatology indications, including RA and PMR. The Company began detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the United States by the Company's distribution partner, Mundipharma International Corporation Limited (Mundipharma).

On November 18, 2013, the Company entered into agreements with AstraZeneca pursuant to which the Company acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with non-steroidal anti-inflammatory drugs (NSAIDs) in the United States. VIMOVO (naproxen/esomeprazole magnesium) is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core. VIMOVO was originally developed by Pozen Inc. (Pozen) together with AstraZeneca pursuant to an exclusive global collaboration and license agreement under which AstraZeneca and Pozen agreed to co-develop VIMOVO and AstraZeneca obtained exclusive rights to commercialize VIMOVO worldwide. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of OA, RA, and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

Under the asset purchase agreement with AstraZeneca, the Company acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the investigational new drug application (IND) and new drug application (NDA) for VIMOVO in the United States, AstraZeneca's interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. In addition, AstraZeneca assigned to the Company its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States. For accounting purposes, the acquisition of the U.S. rights to VIMOVO was treated as a business combination. Collectively, these transactions are referred to as the VIMOVO Acquisition.

In December 2013, as a result of its acquisition of the U.S. rights to VIMOVO, the Company recognized revenues under the transition agreement with AstraZeneca. The Company announced the availability of Horizon-labeled VIMOVO on January 2, 2014, at which time it also began promotion with its primary care sales force and began direct recording of VIMOVO revenue under the transition agreement.

## **Table of Contents**

On March 18, 2014, the Company, Vidara Therapeutics Holdings LLC, a Delaware limited liability company ( Holdings ), Vidara, Hamilton Holdings (USA), Inc., a Delaware corporation and an indirect wholly-owned subsidiary of Vidara ( U.S. HoldCo ), and Hamilton Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of U.S. HoldCo ( Merger Sub ), entered into a Transaction Agreement and Plan of Merger (the Merger Agreement ). Upon consummation of the Merger on September 19, 2014 (the Closing ), the security holders of HPI (excluding the holders of HPI s convertible notes) owned approximately 74% of the Company and Holdings owned approximately 26% of the Company. At the Closing, New Horizon made a cash payment of \$210,871 to Holdings and \$2,750 to Citibank N.A. as escrow agent under an escrow agreement associated with the Merger.

As a result of the Merger, the Company began marketing ACTIMMUNE<sup>®</sup>, a bioengineered form of interferon gamma-1b, a protein that acts as a biologic response modifier, in the United States. ACTIMMUNE is approved by the FDA for use in children and adults with chronic granulomatous disease ( CGD ) and severe, malignant osteopetrosis ( SMO ). ACTIMMUNE is indicated for reducing the frequency and severity of serious infections associated with CGD and for delaying time to disease progression in patients with SMO.

In connection with the Merger, on June 17, 2014, the Company entered into a senior secured credit facility with certain lenders and Citibank, N.A., as administrative agent and collateral agent, that provided the Company with \$300,000 in financing over a five-year period (the Senior Secured Credit Facility ). The Company borrowed the full \$300,000 available under the Senior Secured Credit Facility on September 19, 2014 and used a portion of the proceeds to provide the cash payment of \$213,621 for the Merger and to pay certain transaction related expenses, and is using the balance for general corporate purposes.

On October 17, 2014, the Company announced the acquisition of the U.S. rights to PENNSAID 2% from Nuvo for a one-time payment of \$45,000 in cash. PENNSAID 2% is approved in the United States for the treatment of the pain of OA of the knee(s). As part of the acquisition, the Company entered into an eight-year exclusive supply agreement with Nuvo and the Company expects to begin selling PENNSAID 2% in early January 2015. The Company plans to expand its primary care sales force of 260 representatives by approximately 75 additional representatives and include PENNSAID 2% in its *Prescriptions Made Easy* ( PME ) specialty pharmacy program.

The financial statements are prepared on a going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business. As of September 30, 2014, the Company had cash and cash equivalents totaling \$248,781. For the nine months ended September 30, 2014, the Company s operating activities provided \$17,470 in cash. The Company believes that it has sufficient liquidity and capital resources to conduct its operations based on the Company s current expectations of continued revenue growth. However, the Company is highly dependent in the near term on the commercial success of DUEXIS, VIMOVO, ACTIMMUNE and RAYOS in the U.S. market. From its inception through 2013, the Company had incurred net operating losses and negative cash flows from operations. In order to continue its operations, the Company must continue to generate sufficient revenue and achieve profitable operations. If that does not occur, the Company s plan is to obtain additional debt or equity financing. There can be no assurance, however, that such financing will be available or on terms acceptable to the Company. These uncertainties and lack of commercial operating history raise substantial doubt about the Company s ability to continue as a going concern.

## **NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### *Segment Information*

The Company operates as one segment. Management uses one measure of profitability and does not segment its business for internal reporting.

### *Use of Estimates*

The preparation of the accompanying condensed consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### *Foreign Currency Translation and Transactions*

The reporting currency of the Company and its subsidiaries is the U.S. dollar.

The U.S. dollar is the functional currency for the Company s U.S. based businesses and its subsidiaries in Ireland, Bermuda and Luxembourg. Other foreign subsidiaries have the following functional currencies: Switzerland (Euro), Germany (Euro) and U.K. (British Pound). Foreign currency-denominated assets and liabilities of these subsidiaries are translated into U.S. dollars based on exchange rates prevailing at the end of

## Edgar Filing: Horizon Pharma plc - Form 10-Q

the period, revenues and expenses are translated at average exchange rates prevailing during the corresponding period, and shareholders' equity (deficit) accounts are translated at historical exchange rates as of the date of any equity transaction. The effects of foreign exchange gains and losses arising from the translation of assets and liabilities of those entities where the functional currency is not the U.S. dollar are included as a component of accumulated other comprehensive income (loss).

---

## **Table of Contents**

Gains and losses resulting from foreign currency translations are reflected within the Company's results of operations. During the three months ended September 30, 2014, the Company recorded a loss from foreign currency translations of \$2,754, compared to a foreign currency translation gain of \$1,118 during the three months ended September 30, 2013. During the nine months ended September 30, 2014, the Company recorded a loss from foreign currency translations of \$3,076 compared to a gain from foreign currency translations of \$667 during the nine months ended September 30, 2013. The Company does not currently utilize and has not in the past utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

### *Revenue Recognition*

Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured. Some of the Company's agreements contain multiple elements and in accordance with these agreements, the Company may be eligible for upfront license fees, marketing or commercial milestones and payment for product deliveries.

### *Revenue from Product Deliveries*

The Company recognizes revenue from the delivery of its products when delivery has occurred, title has transferred, the selling price is fixed or determinable, collectability is reasonably assured and the Company has no further performance obligations. In addition, revenue is only recognized when the right of return no longer exists (which is the earlier of the product being dispensed through patient prescriptions or the expiration of the right of return) or when product returns can be reasonably estimated. Due to the Company's ability to reasonably estimate and determine allowances for product returns, rebates and discounts based on its own internal data for DUEXIS and RAYOS or data relating to prior sales of VIMOVO and ACTIMMUNE received in connection with the acquisition of those products, the Company recognizes revenue at the point of sale to wholesale pharmaceutical distributors and retail chains for all currently distributed products.

### *Revenue from Upfront License Fees*

The Company recognizes revenues from the receipt of non-refundable, upfront license fees. In situations where the licensee is able to obtain stand-alone value from the license and no further performance obligations exist on the Company's part, revenues are recognized on the earlier of when payments are received or collection is reasonably assured. Where continuing involvement by the Company is required in the form of technology transfer, product manufacturing or technical support, revenues are deferred and recognized over the term of the agreement.

### *Revenue from Milestone Receipts*

Milestone payments are recognized as revenue based on achievement of the associated milestones, as defined in the relevant agreements. Revenue from a milestone achievement is recognized when earned, as evidenced by acknowledgment from the Company's partner, provided that (1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (2) the milestone represents the culmination of an earnings process and (3) the milestone payment is non-refundable. If any of these criteria are not met, revenue from the milestone achievement is recognized over the remaining minimum period of the Company's performance obligations under the agreement.

The Company anticipates revenues will continue to result from distribution, marketing, manufacturing and supply agreements with third parties in Europe and certain Asian, Latin American and other countries with respect to LODOTRA.

Under the manufacturing and supply agreements with Mundipharma Medical Company (Mundipharma Medical), Mundipharma Medical agreed to purchase LODOTRA exclusively from the Company at a price based on a specified percentage of the average net selling price (ANSP) for sales in a given country, subject to a minimum price. Mundipharma Medical has a nine-month period from purchase date to request an ANSP adjustment. If the ANSP is lower than the actual purchase price, then Mundipharma Medical would receive a price adjustment. Revenue for products sold to Mundipharma Medical is recognized upon delivery at the minimum price, as no contractual right of return exists. The difference between the actual selling price and the minimum price is recorded as deferred revenue until such time as adjustments for product returns, rebates and discounts can be reliably estimated or the nine-month ANSP adjustment period passes, at which time any previously deferred revenue would be recognized as revenue. As of September 30, 2014 and December 31, 2013, deferred revenues related to the sale of LODOTRA were \$755 and \$615, respectively. Additionally, as of September 30, 2014 and December 31, 2013, deferred revenues related to milestone and upfront payments received under existing agreements were \$7,574 and \$8,682, respectively.





## **Table of Contents**

### *Contractual Allowances*

#### *Product Sales Discounts and Allowances*

The Company records allowances for product returns, rebates and discounts at the time of sale to wholesale pharmaceutical distributors and national and regional retail chains. The Company is required to make significant judgments and estimates in determining some of these allowances. If actual results differ from its estimates, the Company will be required to make adjustments to these allowances in the future.

#### *Product Launch Discounts*

The Company has offered additional discounts to wholesale distributors for product purchased at the time of product launch. The Company has recorded these discounts as an allowance against accounts receivable and a reduction of revenue when orders were placed.

#### *Customer Rebates*

The Company participates in certain commercial rebate programs. Under these rebate programs, the Company pays a rebate to the commercial entity or third-party administrator of the program. The Company accrues estimated rebates based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel and records the rebate as a reduction of revenue.

#### *Distribution Service Fees*

The Company includes distribution service fees paid to its wholesalers for distribution and inventory management services as a reduction to revenue. The estimates are based on contractually determined fees, typically as a percentage of revenue.

#### *Co-Pay Assistance*

The Company offers discount programs to patients under which the patient receives a discount on his or her prescription. The Company reimburses pharmacies for this discount through a third-party vendor. The Company records the total amount of estimated discounts for sales recorded in the period as a reduction of revenue based on a combination of actual invoices received and an estimate of discounts to be paid for product in the sales channel based on historical information.

#### *Sales Returns*

Consistent with industry practice, the Company maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the product expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date and up to one year after its expiration date. The right of return expires on the earlier of one year after the product expiration date or the time that the product is dispensed to the patient. The majority of product returns result from product dating, which falls within the range set by the Company's policy, and are settled through the issuance of a credit to the customer. The estimate of the provision for returns is based upon the Company's historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which the customer may return product. This period is known to the Company based on the shelf life of products at the time of shipment. The Company records sales returns as an allowance against accounts receivable and a reduction of revenue.

#### *Prompt Pay Discounts*

As an incentive for prompt payment, the Company offers a 2% cash discount to customers. The Company expects that all customers will comply with the contractual terms to earn the discount. The Company records the discount as an allowance against accounts receivable and a reduction of revenue.

#### *Government Rebates and Chargebacks*

##### *Government Rebates*

The Company participates in certain federal government rebate programs, such as Medicare and Medicaid. The Company accrues estimated rebates based on percentages of product sold to qualified patients, estimated rebate percentages and estimated levels of inventory in the distribution channel that will be sold to qualified patients, and the Company records the rebate as a reduction of revenue.

*Government Chargebacks*

The Company provides discounts to federal government qualified entities with whom the Company has contracted. These federal entities purchase products from the wholesale pharmaceutical distributors at a discounted price, and the wholesale pharmaceutical distributors then charge back to the Company the difference between the current retail price and the contracted price that the federal entities paid for the products. The Company accrues estimated chargebacks based on contract prices and sell-through sales data obtained from third party information and the Company records the chargeback as a reduction of revenue.

## **Table of Contents**

### *Bad Debt Expense*

The Company's products are sold to wholesale distributors and retail chains through manufacturing and supply agreements. For the three and nine months ended September 30, 2014 and for the years ended December 31, 2013, 2012 and 2011, the Company did not record a bad debt expense related to its accounts receivable balances. Accordingly, the Company has not established a reserve for bad debt expense. The Company will continue to monitor its accounts receivable balances to determine the impact, if any, of such factors as changes in customer concentration, credit risk and the realizability of its accounts receivable would require a bad debt reserve allowance in subsequent periods.

### *Cost of Goods Sold*

The Company recognizes cost of goods sold in connection with its sale of DUEXIS, VIMOVO, ACTIMMUNE and RAYOS/LODOTRA.

Cost of goods sold for DUEXIS includes all costs directly related to the acquisition of product from the Company's third-party manufacturers, including freight charges and costs of distribution.

Cost of goods sold for VIMOVO includes all costs directly related to the acquisition of product from AstraZeneca and/or a third-party manufacturer, amortization of intellectual property, royalty accretion expense and any changes in estimate associated with the contingent royalty liability as described in the accrued contingent royalty accounting policy below.

Cost of goods sold for ACTIMMUNE includes all costs directly related to the acquisition of ACTIMMUNE from the Company's third party manufacturer, Boehringer Ingelheim RVC GmbH & co KG (Boehringer Ingelheim), including freight charges and other direct expenses such as insurance and amortization of intellectual property, royalty accretion expense and any changes in estimate associated with the contingent royalty liability as described in the accrued contingent royalty accounting policy below.

Cost of goods sold for RAYOS includes all costs directly related to the acquisition of product from the Company's third-party manufacturers, including freight charges and costs of distribution, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

Cost of goods sold for LODOTRA includes raw material costs, costs associated with third parties who manufacture LODOTRA for the Company, supply chain costs, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

### *Inventories*

Inventories are stated at the lower of cost or market value using the first-in, first-out method. Inventories consist of raw materials, work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. The Company's inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs.

Inventories exclude product sample inventory, which is included in other current assets and is expensed as a component of sales and marketing expense when provided to physicians or healthcare providers. As of September 30, 2014 and December 31, 2013, the Company had product sample inventory of \$3,628 and \$1,323, respectively.

### *Preclinical Studies and Clinical Trial Accruals*

The Company's preclinical studies and clinical trials have historically been conducted by third-party contract research organizations and other vendors. Preclinical study and clinical trial expenses are based on the services received from these contract research organizations and vendors. Payments depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients and site initiation. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts the accrual accordingly. To date, the Company has had no significant adjustments to accrued clinical expenses.

### *Net Loss Per Share*

## Edgar Filing: Horizon Pharma plc - Form 10-Q

Basic net loss per share is computed by dividing net loss by the weighted-average number of ordinary shares outstanding during the period. For the periods presented, the Company's potential dilutive shares, which include ordinary shares issuable upon the exercise of outstanding stock options, unvested restricted stock units, warrants to purchase ordinary shares and ordinary shares associated with the potential conversion of the Convertible Senior Notes have not been included in the computation of diluted net loss per share for the periods presented in which there is a net loss as the result would be anti-dilutive. Such potentially dilutive shares are excluded when the effect would be to reduce net loss per share.

**Table of Contents**

*Cash and Cash Equivalents*

Cash and cash equivalents primarily consist of cash balances in banks and money market funds. The Company's policy is to invest excess cash in money market funds, which are generally of a short-term duration based upon operating requirements.

*Restricted Cash*

Restricted cash consists of balances included in interest-bearing money market accounts required by a vendor for the Company's sponsored employee credit card program and by the lessor for the Company's Deerfield office. As of both September 30, 2014 and December 31, 2013, the Company had restricted cash in the amount of \$738.

*Fair Value of Financial Instruments*

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities.

At December 31, 2013 and at the final measurement date of June 27, 2014, the estimated fair value of the Company's derivative liability related to the convertible portion of its 5.00% Convertible Senior Notes due 2018 (the Convertible Senior Notes) was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, the Company concluded that these inputs were Level 3 inputs.

*Business Combinations*

The Company accounts for business combinations in accordance with the guidance in ASC 805, *Business Combinations*, in which acquired assets and liabilities are measured at their respective estimated fair values as of the acquisition date. The Company may be required, as in the case of intangible assets or contingent royalties, to determine the fair value associated with these amounts by estimating the fair value using an income approach under the discounted cash flow method, which may include revenue projections and other assumptions made by the Company to determine the fair value.

*Property and Equipment, Net*

Property and equipment are stated at cost less accumulated depreciation. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets for financial reporting purposes and an accelerated method for income tax reporting purposes. Upon retirement or sale of an asset, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations. Repair and maintenance costs are charged to expenses as incurred and improvements are capitalized.

Leasehold improvements are amortized on a straight-line basis over the term of the applicable lease, or the useful life of the assets, whichever is shorter.

Depreciation and amortization periods for the Company's property and equipment are as follows:

Machinery and equipment	5-7 years
Furniture and fixtures	3-5 years
Computer equipment	3 years
Software	3 years
Trade show equipment	3 years

Software includes internal-use software acquired and modified to meet the Company's internal requirements. Amortization commences when the software is ready for its intended use.



**Table of Contents***Intangible Assets*

Definite-lived intangible assets are amortized over their estimated useful lives. The Company reviews its intangible assets when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. The Company measures fair value based on the estimated future discounted cash flows associated with these assets in addition to other assumptions and projections that the Company deems to be reasonable and supportable. The estimated useful lives for all identified intangible assets that are subject to amortization are as follows:

<b>Intangible asset</b>	<b>Estimated Useful Life (in years)</b>
LODOTRA and RAYOS developed technology	12
VIMOVO intellectual property	5
ACTIMMUNE developed technology	13
Customer relationships	10

Indefinite-lived intangible assets consist of capitalized in-process research and development ( IPR&D ). IPR&D assets represent capitalized incomplete research projects that the Company acquired through business combinations. Such assets are initially measured at their acquisition date fair values and are tested for impairment, until completion or abandonment of R&D efforts associated with the projects. An IPR&D asset is considered abandoned when R&D efforts associated with the asset have ceased, and there are no plans to sell or license the asset or derive value from the asset. At that point, the asset is considered to be disposed of and is written off. Upon successful completion of each project, the Company will make a determination about the then-remaining useful life of the intangible asset and begin amortization. The Company tests its indefinite-lived intangibles, including IPR&D assets, for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired.

*Research and Development Expenses*

Research and development expenses include, but are not limited to, payroll and other personnel expenses, consultant expenses, expenses incurred under agreements with contract research organizations to conduct clinical trials and expenses incurred to manufacture clinical trial materials.

*Sales and Marketing Expenses*

Sales and marketing expenses consist principally of payroll of sales representatives and marketing and support staff, travel and other personnel-related expenses, marketing materials and distributed sample inventories. In addition, sales and marketing expenses include the Company's medical affairs expenses, which consist of expenses related to scientific publications, health outcomes, biostatistics, medical education and information, and medical communications.

*Concentration of Credit Risk and Other Risks and Uncertainties*

Financial instruments that may potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents. The Company's cash and cash equivalents are invested in deposits with various banks in the United States, Ireland, Switzerland and Germany that management believes are creditworthy. At times, deposits in these banks may exceed the amount of insurance provided on such deposits. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's LODOTRA sales contracts are principally denominated in Euros and, therefore, its revenues are subject to foreign currency risk.

To achieve profitable operations, the Company must successfully develop, obtain regulatory approval for, manufacture and market its products and product candidates, and/or acquire or in-license products from third parties. There can be no assurance that any additional products can be developed, will be approved for marketing by the regulatory authorities, or can be manufactured at an acceptable cost and with appropriate performance characteristics or that any new or existing products can be successfully marketed, acquired or in-licensed by the Company. These factors could have a material adverse effect on the Company's operations.

The Company relies on third parties to manufacture its commercial supplies of DUEXIS, VIMOVO, ACTIMMUNE and RAYOS/LODOTRA. The commercialization of any of its products or product candidates could be stopped, delayed or made less profitable if those third parties fail to provide the Company with sufficient quantities of product or fail to do so at acceptable quality levels or prices.





**Table of Contents**

The Company is required to maintain compliance with applicable Swiss laws with respect to its Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. The Company reviews on a regular basis whether Horizon Pharma AG is overindebted. As of September 30, 2014, Horizon Pharma AG was not overindebted. However, Horizon Pharma AG has previously been overindebted, including at December 31, 2013. The Company will continue to monitor and review Horizon Pharma AG's financial position and, as necessary, will address any overindebtedness until such time as Horizon Pharma AG generates positive income at a statutory level, which could require the Company to have cash at Horizon Pharma AG in excess of its near term operating needs and could affect the Company's ability to have sufficient cash at its other operating subsidiaries to meet its near term operating needs. As of September 30, 2014 and December 31, 2013, Horizon Pharma AG had cash and cash equivalents of \$3,651 and \$3,476, respectively. Based upon the cash and cash equivalents held by Horizon Pharma AG as of September 30, 2014 and December 31, 2013, the Company does not expect that its financial position or results of operations will be materially affected by any need to address overindebtedness at Horizon Pharma AG. To date, the overindebtedness of Horizon Pharma AG has not resulted in the need to divert material cash resources from the Company's other operating subsidiaries.

Historically, the Company's accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. For the nine months ended September 30, 2014, the Company's top five customers, AmerisourceBergen, McKesson Corporation, Cardinal Health, Inc., Rochester Drug Company and American Specialty Pharmacy, Inc., accounted for approximately 90% of total consolidated gross sales. For the twelve months ended December 31, 2013, the Company's top five customers, AmerisourceBergen, McKesson Corporation, Cardinal Health, Inc., Mundipharma and Rochester Drug Company, accounted for approximately 89% of total consolidated gross sales.

In addition, four customers, McKesson Corporation, AmerisourceBergen, American Specialty Pharmacy, Inc. and Cardinal Health, Inc., accounted for approximately 85% of the Company's total outstanding accounts receivable balances at September 30, 2014. As of December 31, 2013, McKesson Corporation, AmerisourceBergen, Rochester Drug Company and Cardinal Health, Inc., accounted for approximately 85% of the Company's total outstanding accounts receivable balances. Historically, the Company has not experienced any losses related to its accounts receivable balances.

*Comprehensive Income (Loss)*

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss) (OCI). OCI includes certain changes in shareholders' equity that are excluded from net income (loss), which consist of foreign currency translation adjustments. In February 2013, the Company adopted on a prospective basis Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* (ASU 2013-02). ASU 2013-02 requires an entity to report the effect of significant reclassifications out of accumulated OCI on the respective line items in net income if the amount being reclassified is required under GAAP to be reclassified in its entirety to net income. For other amounts that are not required under GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under GAAP that provide additional detail about those amounts.

*Stock-Based Compensation*

The Company accounts for stock-based compensation using the fair value method. The fair value of awards granted is estimated at the date of grant and recognized as expense on a straight-line basis over the requisite service period with the offsetting credit to additional paid-in capital. For awards with service and/or performance conditions, the total amount of compensation expense to be recognized is based on the number of awards expected to vest and is adjusted to reflect those awards that do ultimately vest. For awards with performance conditions, the Company recognizes the compensation expense if and when the Company concludes that it is probable that the performance condition will be achieved. The Company reassesses the probability of achieving the performance condition at each reporting date. As of September 30, 2014, the Company does not have any awards outstanding that vest based upon performance conditions.

The Company also accounts for stock options issued to non-employees based on the stock options' estimated fair value. The fair value of equity awards granted to non-employees are re-measured at each reporting date, and the resulting change in the fair value associated with such awards, if any, is recognized as a corresponding increase or reduction to stock-based compensation during the period.

**Table of Contents***Accrued Contingent Royalties*

The Company's accrued contingent royalties consist of the contingent royalty obligations assumed by the Company related to the Company's acquisitions of the U.S. rights to VIMOVO and Vidara (ACTIMMUNE). At the time of each acquisition, the Company assigned a fair value to its liability for royalties. The royalty liability was based on anticipated revenue streams utilizing the income approach under the discounted cash flow method. The estimated liability for royalties is increased over time to reflect the change in its present value and accretion expense is recorded as part of cost of goods sold. The Company evaluates the adequacy of the estimated contingent royalty liability at least annually, or whenever events or changes in circumstances indicate that an evaluation of the estimate is necessary. As part of any evaluation, the Company adjusts the carrying value of the liability to the present value of the revised estimated cash flows using the original discount rate. Any decrease or increase to the liability is recorded as an increase or reduction in cost of goods sold. The royalty liability is included in current and long-term accrued royalties on the consolidated balance sheets.

*New Accounting Pronouncements*

From time to time, the Company adopts, as of the specified effective date, new accounting pronouncements issued by the FASB or other standard setting bodies. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

During the quarter ended June 30, 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard will be effective for the Company on January 1, 2017 and early adoption is not permitted. The new standard permits the use of either the retrospective or cumulative effect transition method on adoption. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures, including which transition method it will adopt.

**NOTE 3 EARNINGS PER SHARE**

The following table presents basic and diluted loss per share for the three and nine months ended September 30, 2014 and 2013:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>Basic earnings (loss) per share calculation:</b>				
Net income (loss)	\$ 2,063	\$ (5,492)	\$ (231,956)	\$ (46,104)
Basic weighted average number of ordinary shares outstanding	78,392,971	64,645,677	73,109,603	63,168,797
Net income (loss) per ordinary share	\$ 0.03	\$ (0.08)	\$ (3.17)	\$ (0.73)
<b>Diluted earnings (loss) per share calculation:</b>				
Net income (loss)	\$ 2,063	\$ (5,492)	\$ (231,956)	\$ (46,104)
Basic weighted average number of ordinary shares outstanding	85,687,267	64,645,677	73,109,603	63,168,797
Net income (loss) per ordinary share	\$ 0.02	\$ (0.08)	\$ (3.17)	\$ (0.73)

The following dilutive securities in the table below were excluded from the computation of diluted earnings (loss) per share for the three and nine months ended September 30, 2014 and 2013 due to being anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Stock options		4,236,675	6,718,287	4,236,675
Restricted stock units		903,710	1,637,399	903,710
Warrants		16,114,746	7,825,821	16,114,746
Convertible Senior Notes	27,964,200		27,964,200	



**Table of Contents****NOTE 4 BUSINESS ACQUISITIONS***Vidara acquisition*

On March 18, 2014, the Company, Holdings, Vidara, U.S. HoldCo and Merger Sub, entered into the Merger Agreement. The Merger Agreement provided for the merger of Merger Sub with and into HPI, with HPI continuing as the surviving corporation and as a wholly-owned, indirect subsidiary of Vidara, with Vidara converting to a public limited company and changing its name to Horizon Pharma plc.

At the effective time of the Merger on September 19, 2014 (the *Effective Time*), (i) each share of HPI's common stock issued and outstanding was converted into one ordinary share of New Horizon; (ii) each equity plan of HPI was assumed by New Horizon and each outstanding option under HPI's equity plans was converted into an option to acquire the number of ordinary shares of New Horizon equal to the number of common stock underlying such option immediately prior to the Effective Time at the same exercise price per share as such option of HPI, and each other stock award that was outstanding under HPI's equity plans was converted into a right to receive, on substantially the same terms and conditions as were applicable to such equity award before the Effective Time, the number of ordinary shares of New Horizon equal to the number of shares of HPI's common stock subject to such stock award immediately prior to the Effective Time; (iii) each warrant to acquire HPI's common stock outstanding immediately prior to the Effective Time and not terminated as of the Effective Time was converted into a warrant to acquire, on substantially the same terms and conditions as were applicable under such warrant before the Effective Time, the number of ordinary shares of New Horizon equal to the number of shares of HPI's common stock underlying such warrant immediately prior to the Effective Time; and (iv) the Convertible Senior Notes of HPI remained outstanding and, pursuant to a supplemental indenture entered into effective as of the Effective Time, have become convertible into the same number of ordinary shares of New Horizon at the same conversion rate in effect immediately prior to the Effective Time. Holdings retained ownership of 31,350,000 ordinary shares of New Horizon at the Effective Time. Upon consummation of the Merger (the *Closing*), the security holders of HPI (excluding the holders of HPI's Convertible Senior Notes) owned approximately 74% of New Horizon and Holdings owned approximately 26% of New Horizon. At the Closing, New Horizon made a cash payment of \$210,871 to Holdings and \$2,750 to Citibank N.A. as escrow agent under an escrow agreement associated with the Merger.

The total consideration for the acquisition of Vidara was \$601,421 representing the \$387,800 market value of the 31,350,000 New Horizon ordinary shares that were held by prior Vidara shareholders immediately following the closing of the Merger plus the cash consideration of \$213,621. The value of the New Horizon ordinary shares of \$387,800 is based on the September 18, 2014 closing stock price of HPI common stock of \$12.37, the last closing price prior to the effective time of the Merger.

Pursuant to ASC Topic 805, *Business Combinations*, the Company accounted for the Merger as a reverse acquisition, under the acquisition method of accounting, with HPI treated as the acquiring company for accounting purposes. Identifiable assets and liabilities of Vidara, including identifiable intangible assets, were recorded based on their estimated fair values as of the date of the closing of the Merger. The excess of the fair value of the net assets acquired over the value of consideration was recorded as a bargain purchase gain. The following table summarizes the preliminary fair values assigned to the assets acquired and the liabilities assumed by the Company pursuant to the Merger, along with the resulting bargain purchase gain:

	<b>Allocation</b>
Cash and cash equivalents	\$ 34,401
Accounts receivable, net	11,838
Inventories	15,422
Other receivable - net working capital adjustment	195
Prepaid expenses	138
Property and equipment, net	289
Deferred tax asset	2,907
Customer relationships	8,100
In-process research and development	66,000
Developed technology	560,000
Accounts payable	(1,781)
Accrued expenses and other current liabilities	(32,372)
Contingent royalties	(33,600)
Other liabilities	(775)
Deferred tax liability	(7,170)
Bargain purchase gain	(22,171)

## Edgar Filing: Horizon Pharma plc - Form 10-Q

Fair value of consideration paid	\$ 601,421
----------------------------------	------------

The fair value of the developed technology, IPR&D, customer relationships and contingent royalties, along with any associated deferred tax assets or liabilities, are preliminary pending final valuations being performed with assistance by an independent appraisal firm.

---

## **Table of Contents**

Inventories acquired included raw materials and finished goods. Fair value of finished goods has been determined based on the estimated selling price, net of selling costs and a margin on the selling costs. Fair value of raw materials has been estimated to equal the replacement cost. A step up in the value of inventory of \$14,218 was recorded in connection with the Merger.

Other tangible assets and liabilities were valued at their respective carrying amounts as management believes that these amounts approximate their current fair values.

Identifiable intangible assets and liabilities acquired included developed technology, in-process research and development and customer relationships. The fair value of intangible assets is based on management's estimates, forecasted financial information and reasonable and supportable assumptions. Estimated useful lives are based on the time periods during which the intangibles are expected to result in incremental cash flows.

Developed technology intangible assets reflect the estimated value of Vidara's rights to the currently marketed ACTIMMUNE product as of the acquisition date. The fair value of developed technology was determined using an income approach. The income approach explicitly recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated direct costs for ACTIMMUNE. Indications of value are developed by discounting these benefits to their present value at a discount rate that reflects the current return requirements of the market. The fair value of developed technology was recorded as an intangible asset as of the acquisition date and subsequently amortized over an estimated remaining life of 13 years.

IPR&D is related to one R&D project for ACTIMMUNE that was incomplete at the time of the Merger. IPR&D is considered separable from the business as the project could be sold to a third party. The fair value of IPR&D was determined using an income approach. The income approach explicitly recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated direct costs. Indications of value are developed by discounting these benefits to their present value at a discount rate that reflects the current return requirements of the market. The fair value of the IPR&D was recorded as an indefinite-lived intangible asset and will be tested for impairment until completion or abandonment of R&D efforts associated with the project.

Customer relationships intangible assets reflect the estimated value of Vidara's customer base for ACTIMMUNE. Vidara's customers as of the acquisition date were predominantly a small group of retail pharmacies with demand for ACTIMMUNE. As such, a significant portion of revenue growth is expected to be generated from existing customers as of the acquisition date. Management assessed the historical customer trends to identify the anticipated attrition. The fair value of customer relationships was recorded as an intangible asset as of the acquisition date and subsequently amortized over an estimated remaining life of 10 years.

The Company has assigned a fair value to a contingent liability for royalties potentially payable under previously existing royalty and licensing agreements related to ACTIMMUNE. The royalties are payable under the terms of the license agreement with Genentech Inc., which was the original developer of ACTIMMUNE and under the terms of its agreement with InterMune's parent company predecessor, Connetics Corporation (which is now part of GlaxoSmithKline). See footnote 13 for details of the percentages payable under both license agreements. The initial fair value of this liability of \$33,600 was determined using a discounted cash flow analysis incorporating the estimated future cash flows of royalty payments resulting from future sales. The estimated liability for royalties will be increased over time to reflect the change in its present value and accretion expense will be recorded as part of cost of goods sold. The estimated liability will be periodically assessed based on events and circumstances and any change will be recorded in New Horizon's consolidated statement of operations.

Deferred tax assets and liabilities arise from acquisition accounting where book values of certain assets and liabilities differ from their tax bases. Deferred tax assets and liabilities are recorded at the currently enacted rates which will be in effect at the time when the temporary differences are expected to reverse in the country where the underlying assets and liabilities are located (United States or Bermuda). Customer relationships intangible assets are located in the United States where a U.S. tax rate of 39% is being utilized and a deferred tax liability is recorded. Developed technology and IPR&D assets are located in Bermuda which does not levy corporate income taxes; accordingly, no deferred tax liabilities were recorded related to these intangible assets.

The excess of the estimated fair values of net assets acquired over the acquisition consideration paid has been recorded as a bargain purchase gain in the condensed consolidated statement of comprehensive income. As previously stated, the total consideration included a fixed number of New Horizon ordinary shares. The bargain purchase gain of \$22,171 is primarily the result of the decrease in the market value of our ordinary shares from the time that the Merger Agreement was signed to the Effective Time of the Merger. The condensed consolidated statement of comprehensive loss for the three and nine months ended September 30, 2014 include ACTIMMUNE revenue of \$2,707, representing net sales during the period following the Merger with Vidara on September 19, 2014.



**Table of Contents*****VIMOVO acquisition***

On November 18, 2013, the Company entered into agreements with AstraZeneca and Pozen pursuant to which the Company acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs, in the United States. VIMOVO (naproxen/esomeprazole magnesium), a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core, was approved by the FDA in 2010 for the relief of the signs and symptoms of OA, RA and AS, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

Pursuant to the transactions contemplated by the asset purchase agreement, the Company acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the IND and NDA for VIMOVO in the United States, AstraZeneca's interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. In consideration for the U.S. rights to VIMOVO, the Company paid to AstraZeneca a one-time upfront cash payment of \$35,000. The Company is also entitled to the benefit of a covenant not to sue granted by Merck Sharp & Dohme Corp. and certain of its affiliates (collectively, Merck) to AstraZeneca, with respect to certain patents owned by AstraZeneca but exclusively licensed to Merck, that cover the manufacture and commercialization of VIMOVO in the United States. In addition, AstraZeneca assigned to the Company its amended and restated collaboration and license agreement for the United States with Pozen pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States. The terms of the amended and restated collaboration and license agreement for the United States with Pozen (the Pozen license agreement) are described below.

In November 2013, in connection with the closing of the transactions contemplated by the asset purchase agreement, the Company also entered into a license agreement with AstraZeneca, a supply agreement with AstraZeneca's affiliate, AstraZeneca LP, and certain other agreements that are described below. The Company also executed a transition agreement with AstraZeneca pursuant to which AstraZeneca transitioned to the Company regulatory and commercial responsibility for VIMOVO in the United States. From the closing of the transaction until December 31, 2013, AstraZeneca continued to commercialize VIMOVO in the United States under AstraZeneca's existing pricing and paid to the Company the net profits recognized on sales of VIMOVO in the United States. Beginning January 2, 2014, the Company commenced commercialization of VIMOVO in the United States on its own behalf and under new pricing for VIMOVO. The Company is responsible for and controls matters relating to VIMOVO in the United States, including responsibility for commercialization of VIMOVO in the United States, responsibility for ongoing developmental and regulatory activities with respect to VIMOVO in the United States and responsibility for the current VIMOVO litigation with respect to the patents the Company purchased under the asset purchase agreement and the patents the Company licensed from Pozen under the Pozen license agreement. AstraZeneca is responsible for and retains control of VIMOVO outside the United States.

In connection with the closing of the transactions contemplated by the asset purchase agreement, the Company entered into a license agreement with AstraZeneca (the AstraZeneca license agreement), pursuant to which AstraZeneca granted the Company an exclusive license under certain intellectual property (including patents, know-how, trademarks, copyrights and domain names) of AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States. AstraZeneca also granted the Company a non-exclusive license under certain intellectual property of AstraZeneca and its affiliates to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States. In addition, AstraZeneca granted the Company a non-exclusive right of reference and use under certain regulatory documentation controlled by AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States and to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States.

Under the AstraZeneca license agreement, the Company granted AstraZeneca a non-exclusive sublicense under such licensed intellectual property and a non-exclusive right of reference under certain regulatory documentation controlled by the Company to manufacture, import, export and perform research and development activities with respect to VIMOVO in the United States but solely for purposes of commercializing VIMOVO outside the United States.

Under the AstraZeneca license agreement, the Company and its affiliates are subject to certain limitations and restrictions on its ability to develop, commercialize and seek regulatory approval with respect to VIMOVO or other products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs (excluding DUEXIS). These limitations and restrictions include, among other things, restrictions on indications for which the Company may commercialize VIMOVO or any such other products, restrictions on the Company's ability to develop or seek regulatory approval with respect to such other products that contain esomeprazole, restrictions on the Company's ability to develop or seek regulatory approval for VIMOVO for any indications other than the indications for which NSAIDs are indicated, and restrictions on the Company's marketing activities with respect to VIMOVO and any such other products.





---

**Table of Contents**

Under the Pozen license agreement, Pozen granted to the Company an exclusive, royalty-bearing license under certain of Pozen's intellectual property in the United States to manufacture, develop and commercialize VIMOVO and other products controlled by the Company that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs (excluding DUEXIS) in the United States.

Under the Pozen license agreement, the Company is required to pay Pozen a flat 10% royalty on net sales of VIMOVO and such other products sold by the Company, its affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of \$5,000 in 2014 and \$7,500 each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen's patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. The Company's obligation to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States. In addition, the Company is obligated to reimburse Pozen for costs, including attorneys fees, incurred by Pozen in connection with VIMOVO patent litigation moving forward, subject to agreed caps.

Under the Pozen license agreement, the Company is responsible for and is required to use diligent and reasonable efforts to commercialize VIMOVO or another qualified product in the United States. The Company also owns and maintains all regulatory filings and marketing approvals in the United States for any such products, including all INDs and NDAs for VIMOVO. Pozen has covenanted that it will not at any time prior to the expiration of the royalty term, and will ensure that its affiliates do not, directly or indirectly, develop or commercialize or license any third party to develop or commercialize certain competing products in the United States.

The Pozen license agreement, unless earlier terminated, will expire upon expiration of the royalty term for all such products in the United States. Either party has the right to terminate the agreement upon any uncured material breach by the other party or upon the bankruptcy or similar proceeding of the other party. The Company also has the right to terminate the Pozen license agreement for cause upon certain defined product failures.

In November 2013, in connection with the asset purchase agreement, the Company, AstraZeneca and Pozen entered into a letter agreement in which Pozen consented to AstraZeneca's assignment of the Pozen license agreement to the Company and that addresses the rights and responsibilities of the parties in relation to the Pozen license agreement and the amended and restated collaboration and license agreement between Pozen and AstraZeneca for territories outside the United States (the Pozen-AstraZeneca license agreement). Under the letter agreement, the Company and AstraZeneca agreed to pay Pozen milestone payments upon the achievement by the Company and AstraZeneca, collectively, of certain annual aggregate global sales thresholds ranging from \$550,000 to \$1,250,000 with respect to products licensed by Pozen to the Company under the Pozen license agreement and to AstraZeneca under the Pozen-AstraZeneca license agreement. The aggregate milestone payment amount that may be owed by AstraZeneca and the Company, collectively, under the letter agreement is \$260,000, with the amount payable by each of the Company and AstraZeneca with respect to each milestone to be based upon the proportional sales achieved by each of the Company and AstraZeneca, respectively, in the applicable year.

The letter agreement will terminate with respect to Pozen and the Company upon the termination of the Pozen license agreement and will terminate with respect to Pozen and AstraZeneca upon the termination of the Pozen-AstraZeneca license agreement.

In November 2013, in connection with the asset purchase agreement, the Company entered into a supply agreement with AstraZeneca pursuant to which AstraZeneca agreed to supply VIMOVO to the Company for commercialization in the United States through December 31, 2014. Under the supply agreement, AstraZeneca will supply the quantity of VIMOVO that the Company orders, both for the Company's own use and for use by the Company's sublicensees, on a transitional basis through December 31, 2014. The Company agreed to pay a set price agreed to by the Company and AstraZeneca for quantities of VIMOVO supplied by AstraZeneca under the supply agreement.

The supply agreement will expire on December 31, 2014, unless terminated earlier as described herein. The supply agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party. Additionally, the Company has the right to terminate the supply agreement at any time upon 120 days prior written notice to AstraZeneca or immediately upon written notice if the existing regulatory approval of VIMOVO is suspended for any reason or if any regulatory authority provides a warning letter or other official documentation expressing major and significant concerns from a regulatory perspective with AstraZeneca's or its affiliates' or third party manufacturer's manufacturing of VIMOVO. Additionally, the supply agreement will automatically terminate upon any termination of the AstraZeneca license agreement.

**Table of Contents**

Pursuant to ASC Topic 805, *Business Combinations*, the Company accounted for the acquisition of the U.S. rights to VIMOVO under the acquisition method of accounting, in which the Company recognized and accounted for the acquisition of the U.S. rights to VIMOVO as a business combination. Net tangible and intangible assets acquired and royalty liabilities assumed were recorded based upon their respective estimated fair values as of the acquisition date. The following table shows the fair values assigned to the assets acquired and liabilities assumed by the Company as part of the asset purchase agreement:

	<b>Allocation</b>
Samples inventory	\$ 287
VIMOVO intellectual property	67,705
Royalty liabilities	(32,992)
 Total cash consideration paid	 \$ 35,000

The valuation of the intellectual property acquired, an identifiable intangible asset, was based on management's estimates, forecasted financial information and reasonable and supportable assumptions. The allocation was generally based on the Company's estimated fair value of the rights to payments with respect to U.S. revenue associated with VIMOVO which were acquired in the transaction. This estimated fair value was determined using the income approach under the discounted cash flow method. Significant assumptions used in valuing the intellectual property intangible asset included revenue projections through 2030 based on assumptions relating to pricing and reimbursement rates and market size and market penetration rates, cost of goods sold based on current manufacturing experience, general and administrative expenses, sales and marketing expenses, and research and development expenses for clinical and regulatory support. The calculated value of the VIMOVO intellectual property intangible asset is amortized using the straight-line method over an estimated useful life of 61.5 months.

Additionally, the Company assigned a fair value to its liability for royalties. The royalty liability was based on anticipated revenue streams utilizing the income approach under the discounted cash flow method. As a result, the Company recorded \$33,000 of fair value royalty payments due to Pozen, of which \$24,500 was guaranteed during the years 2014 through 2018 and \$8,500 was contingent on meeting certain revenue targets. The estimated liability for royalties is increased over time to reflect the change in its present value and accretion expense is recorded as part of cost of goods sold. During the second quarter of 2014, based on higher sales of VIMOVO during the six months June 30, 2014 versus the Company's original expectations and the Company's adjusted expectations for future VIMOVO sales, the Company recorded a charge of \$13,033 to cost of goods sold to increase the carrying value of the contingent royalties to reflect the updated estimates.

***PENNSAID acquisition***

On October 17, 2014, the Company announced the acquisition of the U.S. rights to PENNSAID® 2% from Nuvo for a one-time payment of \$45,000 in cash. PENNSAID 2% is approved in the United States for the treatment of the pain of OA of the knee(s). As part of the acquisition, the Company entered into an eight-year exclusive supply agreement with Nuvo and the Company expects to begin selling PENNSAID 2% in early January 2015. The Company plans to expand its primary care sales force of 260 representatives by approximately 75 additional representatives and include PENNSAID 2% in the PME specialty pharmacy program.

***Pro Forma Information***

The following table represents the consolidated financial information for the Company on a pro forma basis, assuming that both the Merger and the acquisition of the U.S. rights to VIMOVO occurred as of January 1, 2013. The historical financial information has been adjusted to give effect to pro forma items that are directly attributable to the Merger and are expected to have a continuing impact on the consolidated results. These items include, among others, adjustments to record the amortization of definite-lived intangible assets, interest expense, debt discount and deferred financing costs associated with the debt in connection with the acquisitions. Additionally, the following table sets forth unaudited financial information and has been compiled from historical financial statements and other information, but is not necessarily indicative of the results that actually would have been achieved had the transactions occurred on the dates indicated or that may be achieved in the future.

	<b>For the Nine Months Ended September 30,</b>					
	<b>2014</b>			<b>2013</b>		
As reported	Pro-forma adjustments	Pro-forma (Unaudited)	As reported	Pro-forma adjustments	Pro-forma (Unaudited)	

Edgar Filing: Horizon Pharma plc - Form 10-Q

	(Unaudited)				(Unaudited)	
Net revenues	\$ 193,114	\$ 50,565	\$ 243,679	\$ 43,936	\$ 61,752	\$ 105,688
Net loss	(231,956)	(5,104)	(237,060)	(46,104)	(57,189)	(103,293)
Loss per share: Basic and diluted	\$ (3.17)	\$ (0.07)	\$ (3.24)	\$ (0.73)	\$ (0.91)	\$ (1.64)

**Table of Contents****NOTE 5 INVENTORIES**

Inventories are stated at the lower of cost or market value. Inventories consist of raw materials, work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. The Company's inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs. Inventories exclude product sample inventory, which is included in other current assets and is expensed as a component of sales and marketing expense when provided to physicians or healthcare providers.

In connection with the Merger, the ACTIMMUNE inventory was stepped up in value to \$14,218. As of September 30, 2014, the remaining balance of ACTIMMUNE inventory step-up was \$12,678.

The components of inventories as of September 30, 2014 and December 31, 2013, are summarized as follows:

	September 30, 2014	December 31, 2013
Raw materials	\$ 253	\$ 91
Work-in-process	1,624	522
Finished goods	21,971	8,088
Net inventories	\$ 23,848	\$ 8,701

**NOTE 6 PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current assets as of September 30, 2014 and December 31, 2013, consisted of the following:

	September 30, 2014	December 31, 2013
Product samples inventory	\$ 3,628	\$ 1,323
Prepaid software license fees	1,309	855
Prepaid clinical trial studies	233	688
Prepaid co-pay expenses	523	621
Prepaid marketing expenses	121	381
Prepaid insurance	249	379
Prepaid FDA product and manufacturing fees	720	312
Other prepaid expenses	595	329
Total prepaid and other current assets	\$ 7,378	\$ 4,888

**NOTE 7 PROPERTY AND EQUIPMENT**

Property and equipment as of September 30, 2014 and December 31, 2013, consisted of the following:

	September 30, 2014	December 31, 2013
Machinery and equipment	\$ 2,800	\$ 2,367
Furniture and fixtures	215	113
Computer equipment	2,031	2,160
Software	1,404	775

## Edgar Filing: Horizon Pharma plc - Form 10-Q

Trade show equipment	372	228
Leasehold improvements	1,331	783
	8,153	6,426
Less-accumulated depreciation	(3,497)	(2,646)
<b>Net property and equipment</b>	<b>\$ 4,656</b>	<b>\$ 3,780</b>

Depreciation expense was \$413 and \$302 for the three months ended September 30, 2014 and 2013, respectively, and was \$1,193 and \$861 for the nine months ended September 30, 2014 and 2013, respectively.

**Table of Contents****NOTE 8 INTANGIBLE ASSETS**

The Company's intangible assets consist of developed technology related to the Company's approved products LODOTRA in Europe along with ACTIMMUNE and RAYOS in the United States and VIMOVO intellectual property rights in the United States.

On November 18, 2013, in connection with the Company's acquisition of the U.S. rights to VIMOVO, the Company capitalized \$67,705 for the U.S. intellectual property rights of VIMOVO to intangible assets.

On September 19, 2014, in connection with the Merger with Vidara, the Company capitalized \$560,000 of developed technology, \$66,000 of IPR&D and \$8,100 of customer relationships.

The Company tests its intangible assets for impairment when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. The Company does not believe there have been any circumstances or events that would indicate that the carrying value of any of its intangible assets have been impaired at September 30, 2014 or December 31, 2013.

As of September 30, 2014 and December 31, 2013, intangible assets consisted of the following:

	September 30, 2014				December 31, 2013			
	Cost Basis	Accumulated Amortization	Currency Translation	Net Book Value	Cost Basis	Accumulated Amortization	Currency Translation	Net Book Value
Developed technology	\$ 644,779	\$ (24,357)	\$ (6,923)	\$ 613,499	\$ 84,779	\$ (17,823)	\$ (2,136)	\$ 64,820
VIMOVO intellectual property	67,705	(11,339)		56,366	67,705	(1,431)		66,274
In-process research and development	66,000			66,000				
Customer relationships	8,100	(27)		8,073				
Total other intangible assets	141,805	(11,366)		130,439	67,705	(1,431)		66,274
Total intangible assets	\$ 786,584	\$ (35,723)	\$ (6,923)	\$ 743,938	\$ 152,484	\$ (19,254)	\$ (2,136)	\$ 131,094

Amortization expense was \$6,413 and \$1,680 for the three months ended September 30, 2014 and 2013, respectively, and was \$16,469 and \$4,977 for the nine months ended September 30, 2014 and 2013. IPR&D is not amortized until successful completion of the project. As of September 30, 2014, estimated future amortization expense was as follows:

2014 (remainder of the year)	\$ 15,984
2015	63,933
2016	63,933
2017	63,933
2018 and thereafter	470,155
Total	\$ 677,938

**NOTE 9 ACCRUED TRADE DISCOUNTS AND REBATES**

Accrued trade discounts and rebates as of September 30, 2014 and December 31, 2013, consisted of the following:

September 30, 2014	December 31, 2013
-----------------------	----------------------

Edgar Filing: Horizon Pharma plc - Form 10-Q

Contractual allowances	\$ 55,285	\$ 6,716
Government rebates and chargebacks	15,216	1,407
Total accrued liabilities	\$ 70,501	\$ 8,123



**Table of Contents****NOTE 10 ACCRUED EXPENSES**

Accrued expenses as of September 30, 2014 and December 31, 2013, consisted of the following:

	September 30, 2014	December 31, 2013
Payroll related expenses	\$ 15,109	\$ 9,491
Accrued excise tax gross up	10,617	
Accrued interest	3,731	810
Professional services	1,976	350
Sales and marketing expenses	1,125	1,761
Income taxes	1,005	
Deferred rent	895	755
Clinical and regulatory expenses	307	488
Consulting services	315	283
Contract manufacturing expenses	262	301
Accrued other	4,089	1,687
Total accrued expenses	\$ 39,431	\$ 15,926

In connection with the Merger, any individual who is or was an executive officer or director of HPI or New Horizon and subject to the reporting requirements of Section 16(a) of the Securities Exchange Act of 1934 at any time during the period commencing six months before and ending six months after the closing of the Merger ( Covered Individual ) is subject to an excise tax (15% in 2014) under Section 4985 of the Internal Revenue Code of 1986 on the value of certain stock compensation held at any time during the same period by the covered individual. The excise tax applies to all payments (or rights to payment) granted to the Covered Individuals by HPI or New Horizon in connection with the performance of services if the value of such payment is based on (or determined by reference to) the value of stock in HPI or New Horizon (excluding certain statutory incentive stock options and holdings in tax qualified plans). This includes any outstanding (a) unexercised nonqualified stock options, whether vested or unvested, (b) restricted stock awards that remain subject to forfeiture, (c) unvested restricted stock unit awards and (d) vested but deferred shares, in each case which are held by the Covered Individuals during this twelve month period.

After careful consideration, the New Horizon board of directors concluded that the Company would provide the Covered Individuals with a payment with respect to the excise tax, so that, on a net after-tax basis, they would be in the same position as if no such excise tax had applied to them. As a result, the Company has estimated a liability of \$10,617 for the payments due to those who were Covered Individuals. This amount was recorded by the Company in September 2014 as general and administrative expense on the consolidated statements of comprehensive loss and is included in accrued expenses on the consolidated balance sheet as of September 30, 2014. These payments are expected to be made to the Covered Individuals when the excise tax becomes due and payable in 2015. Should the Company grant stock compensation in connection with the hire of any new executive officers or addition of any new board members who become Covered Individuals at any time during the six month period following the closing of the Merger, an additional excise tax reimbursement payable for such new Covered Individuals will be incurred by the Company and a corresponding liability will be recorded.

**NOTE 11 ACCRUED ROYALTIES**

Changes in the liability for royalties during the nine months ended September 30, 2014 consisted of the following:

Balance as of December 31, 2013	\$ 33,000
Remeasurement of royalty liabilities	13,033
Assumed ACTIMMUNE royalty liabilities	37,309
Royalty payments	(9,715)
Accretion expense	5,617
Balance as of September 30, 2014	79,244

## Edgar Filing: Horizon Pharma plc - Form 10-Q

Less: Current portion	25,876
Accrued royalties long-term	\$ 53,368

During the second quarter of 2014, based on higher sales of VIMOVO during the six months ended June 30, 2014 versus our original expectations and our adjusted expectations for future VIMOVO sales, the Company recorded a charge of \$13,033 to cost of goods sold to increase the amount of the contingent royalty liability to reflect the updated estimates.

**Table of Contents****NOTE 12 FAIR VALUE MEASUREMENTS**

The following tables set forth the Company's financial instruments that are measured at fair value on a recurring basis within the fair value hierarchy. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The following describes three levels of inputs that may be used to measure fair value:

*Level 1* Observable inputs such as quoted prices in active markets for identical assets or liabilities.

*Level 2* Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

*Level 3* Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company utilizes the market approach to measure fair value for its money market funds. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities.

***Assets and liabilities measured at fair value on a recurring basis***

The following table sets forth the Company's financial assets and liabilities at fair value on a recurring basis as of September 30, 2014 and December 31, 2013:

	As of September 30, 2014			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 111,581	\$	\$	\$ 111,581
<b>Total assets at fair value</b>	<b>\$ 111,581</b>	<b>\$</b>	<b>\$</b>	<b>\$ 111,581</b>
	As of December 31, 2013			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 66,817	\$	\$	\$ 66,817
<b>Total assets at fair value</b>	<b>\$ 66,817</b>	<b>\$</b>	<b>\$</b>	<b>\$ 66,817</b>
<b>Liabilities:</b>				
Derivative liability	\$	\$	\$ 109,410	\$ 109,410
<b>Total liabilities at fair value</b>	<b>\$</b>	<b>\$</b>	<b>\$ 109,410</b>	<b>\$ 109,410</b>

In accordance with the pronouncement guidance in ASC 815, *Derivatives and Hedging*, as of December 31, 2013, the conversion option included within the Convertible Senior Notes was deemed to include an embedded derivative, which required the Company to bifurcate and separately account for the embedded derivative as a separate liability on its condensed consolidated balance sheets. The estimated fair value was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, the Company concluded that these inputs were Level 3 inputs.



**Table of Contents**

The following table presents the assumptions used by the Company to determine the fair value of the conversion option embedded in the Convertible Senior Notes as of June 27, 2014, the date the Company's shareholders approved the issuance of shares of the Company's common stock in excess of 13,164,951 shares upon conversion of the Convertible Senior Notes, and December 31, 2013:

	<b>June 27, 2014</b>	<b>December 31, 2013</b>
Stock price	\$15.96	\$7.62
Risk free rate	1.43%	1.69%
Borrowing cost	3.75%	5.0% and 3.5%
Weights		Equal weight
Credit spread (in basis points)	900	930 and 1,170
Volatility	40.00%	40.00%
Initial conversion price	\$5.36	\$5.36
Remaining time to maturity (in years)	4.4	4.9

On June 27, 2014, the Company's shareholders approved the issuance of the Company's ordinary shares in excess of 13,164,951 shares upon conversion of the Convertible Senior Notes. As such, on the date of approval, the derivative liability was re-measured to a final fair value and the entire fair value of the derivative liability of \$324,405 was reclassified to additional paid-in capital. Total losses of \$214,995 from re-measurement of the derivative liability were recorded in its results of operations for the nine months ended September 30, 2014.

**NOTE 13 COMMITMENTS AND CONTINGENCIES***Lease Obligations*

In September 2011, the Company entered into an office lease agreement for 21,182 square feet of office space in Deerfield, Illinois, which was effective August 31, 2011. The initial term of the lease commenced on December 1, 2011, and expires on June 30, 2018. The minimum rent was initially approximately \$30 per month during the first year and increases each year during the initial term, up to approximately \$35 per month after the sixth year. The Company has the option to extend the lease for an additional five-year term, which would commence upon the expiration of the initial term. In August 2012, the Company entered into an amendment to the lease agreement to expand the office space available to it by an additional 4,926 square feet in the same Deerfield, Illinois facility as its existing office space. The initial rent on the additional lease is \$7 per month and will increase up to a maximum of \$8 per month after the sixth year. In December 2013, the Company entered into a second amendment to the lease agreement to expand the office space available to it by an additional 8,352 square feet. The initial rent on the second amendment is \$12 per month and will increase up to a maximum of \$14 per month after the fifth year. In June 2014, the Company entered into a third amendment to the lease agreement to expand the office space available to it by an additional 16,014 square feet. The initial rent on the third amendment is \$24 per month and will increase up to a maximum of \$26 per month after the fifth year. The term of the three amendments to the lease agreement coincide with the original lease agreement and run through June 30, 2018.

The Company also leases its offices in Reinach, Switzerland, Mannheim, Germany and Roswell, Georgia. The Reinach office lease rate is \$7 (6 Swiss Francs) per month, expiring on May 31, 2015. The Mannheim office lease rate is approximately \$7 (5 Euros) per month through December 31, 2014 and \$9 (7 Euros) per month thereafter, expiring on December 31, 2016. The Roswell office lease rate is approximately \$4 per month, expiring October 31, 2018.

On November 4, 2014, the Company entered into a lease agreement for a 10,266 square feet of space in a facility located in Dublin, Ireland. The Lease is for a term of 15 years, commencing on November 4, 2014. For the first five years of the lease, the minimum rent due is 483 (Euro) per year and is payable in equal quarterly payments. On November 5, 2019 and each fifth anniversary thereafter, the rental rate will be set to a current market rate, as determined by the procedures set forth in the lease. The Company has the right to terminate the lease after ten years by giving at least nine months prior notice to the landlord.

**Table of Contents***Annual Purchase Commitments*

In August 2007, the Company entered into a manufacturing and supply agreement with Jagotec AG ( Jagotec ). Under the agreement, Jagotec or its affiliates are required to manufacture and supply RAYOS/LODOTRA exclusively to the Company in bulk. The Company committed to a minimum purchase of RAYOS/LODOTRA tablets from Jagotec for five years from the date of first launch of RAYOS/LODOTRA in a major country, as defined in the agreement, which was in April 2009. At September 30, 2014, the minimum remaining purchase commitment based on tablet pricing in effect under the agreement was \$3,418. The agreement automatically renews on a yearly basis until either party provides two years advance written notice of termination. In April 2014, the agreement automatically renewed, and, therefore, the earliest the current agreement can expire according to this advance notice procedure is April 15, 2017.

In May 2011, the Company entered into a manufacturing and supply agreement with sanofi-aventis U.S., and amended the agreement effective as of September 25, 2013. Pursuant to the agreement, as amended, sanofi-aventis U.S. is obligated to manufacture and supply DUEXIS to the Company in final, packaged form, and the Company is obligated to purchase DUEXIS exclusively from sanofi-aventis U.S. for the commercial requirements of DUEXIS in North America, South America and certain countries and territories in Europe, including the European Union member states and Scandinavia. At September 30, 2014, the Company had a binding purchase commitment to sanofi-aventis U.S. for DUEXIS of \$2,384, which is to be delivered through the fourth quarter of 2014.

In July 2013, Vidara and Boehringer Ingelheim entered into an exclusive supply agreement, which the Company assumed as of result of the Merger. Under the agreement, Boehringer Ingelheim is required to manufacture and supply interferon gamma 1-b to the Company. The Company committed to an annual minimum purchase through July 2020. As of September 30, 2014, the minimum binding purchase commitment to Boehringer Ingelheim was \$27,300 (converted using a Dollar-to-Euro rate of 1.38), which is to be delivered through July 2020.

In November 2013, the Company and AstraZeneca entered into a supply agreement pursuant to which AstraZeneca agreed to supply VIMOVO to the Company for commercialization in the United States through December 31, 2014. As of December 5, 2013, the Company has been providing AstraZeneca with a forecast of its supply requirements, including any forecasts for its sublicensees. The first four months of each forecast is a binding purchase commitment and may not be changed without AstraZeneca's written consent. As of September 30, 2014, the minimum binding purchase commitment to AstraZeneca was \$2,840 and is to be delivered through the fourth quarter of 2014. After 2016, AstraZeneca will no longer be obligated to supply VIMOVO to the Company.

In October 2013, the Company entered into a long-term master manufacturing services and product agreement with Patheon Pharmaceuticals Inc. ( Patheon ), for the supply of finished VIMOVO product. During the term of the agreement, the Company will issue 12-month forecasts of the volume of VIMOVO that the Company expects to order. The first three months of the forecast will be considered binding firm orders. At September 30, 2014, the Company had a binding purchase commitment with Patheon for VIMOVO of \$306.

In October 2014, in connection with the acquisition of the U.S. rights to PENNSAID 2% from Nuvo, the Company and Nuvo, entered into an exclusive supply agreement. Under the supply agreement, Nuvo will manufacture and supply PENNSAID 2% to the Company. The Company has committed to a binding purchase order to Nuvo for delivery of PENNSAID 2% on or before March 1, 2015 of \$1,569. In addition, at least 90 days prior to the first day of each calendar month during the term of the supply agreement, the Company will submit a binding written purchase order to Nuvo for PENNSAID 2% in minimum batch quantities. The initial term of our supply agreement is through December 31, 2022, but the agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party.

*Royalty Agreements*

In connection with the August 2004 development and license agreement with SkyePharma AG ( SkyePharma ) and Jagotec, a wholly-owned subsidiary of SkyePharma, regarding certain proprietary technology and know-how owned by SkyePharma, Jagotec is entitled to receive a single digit percentage royalty on net sales of RAYOS/LODOTRA and on any sub-licensing income, which includes any payments not calculated based on the net sales of RAYOS/LODOTRA, such as license fees, lump sum and milestone payments. Royalty expense recognized in cost of goods sold for the three months ended September 30, 2014 and 2013 was \$451 and \$221, respectively, and for the nine months ended September 30, 2014 and 2013 was \$1,164 and \$551, respectively.

Under the Pozen license agreement, the Company is required to pay Pozen a flat 10% royalty on net sales of VIMOVO and such other products sold by the Company, its affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of \$5,000 in 2014 and \$7,500 each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen's patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. The Company's obligation to pay royalties to Pozen will expire upon the

## Edgar Filing: Horizon Pharma plc - Form 10-Q

later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States.

---

## **Table of Contents**

Under the license agreement with Genentech Inc., which was the original developer of ACTIMMUNE, the Company is obligated to pay royalties to Genentech on its net sales of ACTIMMUNE as follows:

Through November 25, 2014, a royalty of 45% of the first \$3.7 million in net sales achieved in a calendar year, and 10% on all additional net sales in that year;

For the period from November 26, 2014 through May 5, 2018, the royalty payments will be reduced to a 20-30% range for the first tier in net sales and in the 1-9% range for the second tier; and

From May 6, 2018 and for so long as the Company continues to commercially sell ACTIMMUNE, an annual royalty in the low single digits as a percentage of annual net sales.

Under the terms of the agreement with InterMune's parent company predecessor, Connetics Corporation (which is now part of GlaxoSmithKline), the Company is obligated to pay royalties to Connetics on the Company's net sales of ACTIMMUNE as follows:

0.25% of net sales of ACTIMMUNE, rising to 0.5% once cumulative net sales of ACTIMMUNE in the United States surpass \$1.0 billion; and in the event the Company develops and receive regulatory approval for ACTIMMUNE in the indication of scleroderma, the Company will be obligated to pay a royalty of 4% on all net sales of ACTIMMUNE recorded for use in that indication.

The royalty obligations for VIMOVO and ACTIMMUNE are included in accrued royalties on the Company's consolidated balance sheets.

### *Excise Tax Gross Up*

In connection with the Merger, the New Horizon board of directors concluded that the Company would provide the Covered Individuals with a payment with respect to the excise tax on the value of certain stock compensation, so that, on a net after-tax basis, they would be in the same position as if no such excise tax had applied to them. The Company has estimated a liability of \$10,617 for the payments due to those who were Covered Individuals. This amount was recorded by the Company in September 2014 as general and administrative expense on the consolidated statements of comprehensive loss and is included in accrued expenses on the consolidated balance sheet as of September 30, 2014. These payments are expected to be made to the Covered Individuals when the excise tax becomes due and payable in 2015. Should the Company grant stock compensation in connection with the hire of any new executive officers or addition of any new board members who become Covered Individuals at any time during the six month period following the closing of the Merger, an additional excise tax reimbursement payable for such new Covered Individuals will be incurred by the Company and a corresponding liability will be recorded.

### *Contingencies*

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company's management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial condition, results of operations or cash flows. In addition, the Company from time to time has billing disputes with vendors in which amounts invoiced are not in accordance with the terms of their contracts. The Company currently estimates the range of potential disputes to be in the \$0 to \$4,700 range and has not recorded a liability associated with any portion of the disputed amounts as the Company does not believe payment of any such amounts is probable at this time.

### *Indemnification*

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.



## Edgar Filing: Horizon Pharma plc - Form 10-Q

In accordance with its amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. Additionally, the Company has entered, and intends to continue to enter, into separate indemnification agreements with its directors and executive officers. These agreements, among other things, require the Company to indemnify its directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of the Company's directors or executive officers, or any of the Company's subsidiaries or any other company or enterprise to which the person provides services at the Company's request. There have been no claims to date and the Company has a director and officer insurance policy that enables it to recover a portion of any amounts paid for future potential claims.

**Table of Contents****NOTE 14 LEGAL PROCEEDINGS**

On February 15, 2012, the Company received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an Abbreviated New Drug Application ( ANDA ) with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, the Company filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par ) for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or prevent Par from selling a generic version of DUEXIS. In January 2013, the Company filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par s ANDA and/or prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, the Company entered into a settlement agreement ( Par settlement agreement ) and license agreement ( Par license agreement ) with Par relating to its patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both the Company and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

Under the Par license agreement, the Company granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par s generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par s generic version of DUEXIS prior to the generic entry date (collectively, the License ). The License covers all patents owned or controlled by the Company during the term of the Par license agreement that would, absent the License, be infringed by the manufacture, use, sale, offer for sale, or importation of Par s generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the License become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.

Under the Par license agreement, the Company also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by the Company during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par s generic version of DUEXIS in the United States.

The Par license agreement may be terminated by the Company if Par commits a material breach of the agreement that is not cured or curable within 30 days after the Company provides notice of the breach. The Company may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.

On July 15, 2013, the Company received a Paragraph IV Patent Certification from Watson Laboratories, Inc. Florida, known as Actavis Laboratories FL, Inc. ( Watson ), advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised the Company as to the timing or status of the FDA s review of its filing. On August 26, 2013, the Company, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc. (collectively WLF ) seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. The Company and Jagotec have granted WLF a covenant not to sue with respect to US Patent Nos. 6,677,326 and 8,168,218, respectively, and accordingly these patents have been dismissed from the lawsuit. The Markman claim construction hearing took place on October 16, 2014. The Court has not yet set a trial date for the WLF action.

**Table of Contents**

On September 12, 2013, the Company received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. On October 22, 2013, the Company, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. On November 20, 2013, the Company was notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, the Company entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

Currently, patent litigation is pending in the District of New Jersey against four generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and have been consolidated for discovery purposes. They are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, Dr. Reddy's); (ii) Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, Lupin); (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, Mylan); and (iv) Watson Laboratories, Inc. Florida, known as Actavis Laboratories FL, Inc. and Actavis Pharma, Inc. (collectively, Actavis). Patent litigation in the District of New Jersey against a fifth generic company, Anchen Pharmaceuticals Inc. (Anchen), was dismissed after Anchen recertified under Paragraph III. The Company understands that Dr. Reddy's has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy's is now able to commercialize VIMOVO under AstraZeneca's Nexium patent rights. The settlement agreement, however, has no effect on the Pozen VIMOVO patents, which are still the subject of patent litigations. As part of the Company's acquisition of the U.S. rights to VIMOVO, the Company has taken over and is responsible for the patent litigations that include the Pozen patents licensed to the Company under the Pozen license agreement.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. The Company understands the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. The Company understands the Dr. Reddy's notice letters were dated March 11, 2011 and November 20, 2012; the Lupin notice letters were dated June 10, 2011 and March 12, 2014; the Mylan notice letter was dated May 16, 2013; the Actavis notice letters were dated March 29, 2013 and November 5, 2013; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order and has set a pretrial schedule but has not yet set a trial date.

**NOTE 15 DEBT AGREEMENTS**

The Company's outstanding debt balances as of September 30, 2014 and December 31, 2013, consisted of the following:

	September 30, 2014	December 31, 2013
Senior secured credit facility	\$ 300,000	\$
Convertible senior notes	150,000	150,000
Debt discount	(36,179)	(39,238)
Total long-term debt	413,821	110,762
Less: current maturities	116,799	
Long-term debt, net of current maturities	\$ 297,022	\$ 110,762

**Convertible Senior Notes**

On November 18, 2013, the Company entered into note purchase agreements with investors to issue \$150,000 aggregate principal amount of Convertible Senior Notes. The note purchase agreements contain customary representations, warranties, covenants and closing conditions. The Convertible Senior Notes were issued on November 22, 2013. The Company received net proceeds of \$143,598 from the sale of the Convertible Senior Notes, after deducting fees and expenses of \$6,402. The Convertible Senior Notes are governed by an Indenture, dated as of November 22, 2013, between HPI and U.S. Bank National Association, as trustee (the Indenture). The Convertible Senior Notes bear interest at a rate of 5.00% per year, payable in arrears on May 15 and November 15 of each year, which began on May 15, 2014. The Convertible Senior

Edgar Filing: Horizon Pharma plc - Form 10-Q

Notes will mature on November 15, 2018, unless earlier repurchased or converted.

**Table of Contents**

The Company used a portion of the proceeds from the Convertible Senior Notes to purchase \$18,675 related to certain capped call transactions with Deutsche Bank AG, London Branch, and Société Générale (the counterparties). The capped call transactions were comprised of a net settled purchased call option and a net settled sold call option. The Company purchased the call option with an initial strike price of \$5.364, which was equal to the initial conversion price, and sold a call option with a strike price of \$6.705, which is equal to the cap price. The number of options underlying the capped calls was 150,000 or the equivalent to the number of \$1,000 Convertible Senior Notes initially issued by the Company. On September 23, 2014, the counterparties exercised their rights to terminate the capped call transactions. In connection with such termination, the Company received \$14.0 million comprised of \$9.4 million in cash and 384,366 ordinary shares of the Company valued at \$4.6 million, based on the closing stock price of September 22, 2014 of \$11.93 per share and recorded the receipt of the ordinary shares as treasury shares. In addition, in connection with the termination of the capped call transactions, the counterparties and/or their affiliates unwound or will unwind various hedging transactions with respect to the Company's ordinary shares, which could have an effect on the market price of the Company's ordinary shares.

The Convertible Senior Notes were sold at a price equal to 100% of the principal amount thereof and are convertible, under certain conditions, at the option of the holders at any time prior to the close of business on the business day immediately preceding August 15, 2018. Prior to August 15, 2018, the Convertible Senior Notes are convertible, at the option of the holders thereof, only under the following circumstances:

1. *Conversion upon Satisfaction of Sale Price Condition:* If the closing price of the Company's ordinary shares for at least 20 trading days during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day.
2. *Conversion upon Satisfaction of Trading Price Condition:* The Convertible Senior Notes can be surrendered for conversion during the five business day period after any five consecutive trading day period in which the trading price per \$1,000 principal amount of Convertible Senior Notes was less than 98% of the product of the last reported sale price of the Company's ordinary shares and the applicable conversion rate on such date.
3. *Conversion upon Specified Distributions:* If the Company elects to:
  - i. issue to all or substantially all holders of the Company's ordinary shares any rights, options or warrants (other than in connection with a shareholder rights plan) entitling them, for a period of not more than 45 calendar days after the declaration date for such issuance, to subscribe for or purchase the Company's ordinary shares at a price per share that is less than the average of the last reported sale prices of the Company's ordinary shares for the 10 consecutive trading day period ending on, and including, the trading day immediately preceding the declaration date for such issuance; or
  - ii. distribute to all or substantially all holders of the Company's ordinary shares its assets, securities or rights to purchase its securities, which distribution has a per share value, as reasonably determined by the Company's board of directors or a committee thereof, exceeding 10% of the last reported sale price of the Company's ordinary shares on the trading day preceding the date of announcement for such distribution.
4. *Conversion upon Specified Corporate Events:* If (i) a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs or (ii) the Company is party to a consolidation, merger, binding share exchange, or transfer or lease of all or substantially all of its consolidated assets pursuant to which the Company's ordinary shares would be converted into cash, securities or other assets.

On or after August 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date for the Convertible Senior Notes, holders will be able to convert their Convertible Senior Notes at their option at the conversion rate then in effect at any time, regardless of these conditions.

Subject to certain limitations, HPI may settle conversions of the Convertible Senior Notes by paying or delivering, as the case may be, cash, the Company's ordinary shares or a combination of cash and the Company's ordinary shares at HPI's election. If the Company undergoes a

## Edgar Filing: Horizon Pharma plc - Form 10-Q

fundamental change prior to the maturity date of the Convertible Senior Notes, the holders may require HPI to repurchase for cash all or any portion of their Convertible Senior Notes at a price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased, plus accrued and unpaid interest.

The conversion rate for the Convertible Senior Notes was initially 186.4280 ordinary shares per \$1,000 principal amount of Convertible Senior Notes (equivalent to an initial conversion price of approximately \$5.36 per ordinary share). The conversion rate of the Convertible Senior Notes, and the corresponding conversion price, is subject to adjustment for certain events, but will not be adjusted for accrued and unpaid interest. On June 27, 2014, the Company's shareholders approved the issuance of ordinary shares in excess of 13,164,951 shares upon conversion of the Convertible Senior Notes. On June 30, 2014, the Company reclassified the Convertible Senior Notes from long term to short term as conditions for conversion were met.

## Table of Contents

Pursuant to a number of factors outlined in ASC Topic 815, *Derivatives and Hedging*, the conversion option in the Convertible Senior Notes was deemed to include an embedded derivative that required bifurcation and separate accounting. As such, the Company ascertained the value of the conversion option as if separate from the convertible issuance and appropriately recorded that value as a derivative liability. On November 22, 2013, a derivative liability and a corresponding debt discount in the amount of \$40,110 were recorded. The debt discount is being charged to interest expense ratably over the life of the convertible debt. The effective interest rate computed on the Convertible Senior Notes was 11.22%.

The derivative liability was subject to revaluation on a quarterly basis to reflect the market value change of the embedded conversion option. At December 31, 2013, the Company conducted a fair value assessment of the embedded derivative. As a result of the fair value assessment, the Company recorded a \$69,300 expense in its results of operations for the three and twelve months ended December 31, 2013 to properly reflect the fair value of the embedded derivative of \$109,410 as of December 31, 2013. At March 31, 2014, the Company conducted a subsequent fair value assessment to reflect the market value adjustments for the embedded derivative. During the three months ended March 31, 2014, the Company recorded a \$204,030 loss in its results of operations to properly reflect the fair value of the embedded derivative of \$313,440.

On June 27, 2014, the Company's shareholders approved the issuance of the Company's ordinary shares in excess of 13,164,951 shares upon conversion of the Convertible Senior Notes. As such, on the date of approval, the derivative liability was re-measured to a final fair value and the entire fair value of the derivative liability of \$324,405 was reclassified to additional paid-in capital. Total losses of \$214,995 from re-measurement of the derivative liability were recorded in its results of operations for the nine months ended September 30, 2014.

In connection with the Merger, HPI and New Horizon executed a supplemental indenture dated as of September 19, 2014 (the First Supplemental Indenture) with U.S. Bank National Association (the Trustee) to the Indenture. Pursuant to the First Supplemental Indenture, HPI remained the obligor of the Convertible Senior Notes and the Company agreed to fully and unconditionally guaranty the obligations of HPI under the Indenture (the Guaranty). The First Supplemental Indenture also provides that the conversion value of the Convertible Senior Notes will be calculated by reference to the Company's ordinary shares, rather than the common stock of HPI, and any shares issuable upon conversion of the Convertible Senior Notes will be settled in the Company's ordinary shares, rather than shares of the common stock of HPI. In addition, the Company assumed the disclosure obligations required by the Indenture.

On October 23, 2014 and October 27, 2014, the Company entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes. Under the conversion agreements, the holders agreed to convert an aggregate principal amount of \$69,434 of Convertible Senior Notes held by them and the Company agreed to settle such conversions by issuing 12,944,350 ordinary shares. In addition, pursuant to the conversion agreements, the Company made an aggregate cash payment of \$14,614 to the holders for additional exchange consideration and accrued and unpaid interest. The transactions closed on or before October 31, 2014. Immediately following the conversions of the Convertible Senior Notes contemplated by the conversion agreements, \$80,566 in aggregate principal amount of the Convertible Senior Notes remained outstanding.

### **Senior Secured Credit Facility**

On June 17, 2014, the Company entered into the Senior Secured Credit Facility with a group of lenders and Citibank, N.A., as administrative and collateral agent. The Senior Secured Credit Facility is governed by a Credit Agreement dated June 17, 2014. The Senior Secured Credit Facility provides for (i) a committed five-year \$300,000 term loan facility (the Term Loan Facility) with a portion of the proceeds used to effect the Merger and to pay fees and expenses in connection therewith, and with the balance being used for general corporate purposes; (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions; and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder. The initial borrower under the Term Loan Facility is U.S. HoldCo (renamed Horizon Pharma Holdings USA, Inc.). The Credit Agreement allows for the Company and other subsidiaries of the Company to become borrowers under the accordion facility. Loans under the Senior Secured Credit Facility bear interest, at each borrower's option, at a rate equal to either the London Inter-Bank Offer Rate (LIBOR), plus an applicable margin of 8.00% per year (subject to a 1.00% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 7.00% per year. The Company borrowed the full \$300,000 available on the Term Loan Facility on September 19, 2014 as a LIBOR-based borrowing. The Company paid a ticking fee to the applicable lenders of \$3,222 covering the period beginning on the date that was 31 days following the effective date of the Senior Secured Credit Facility and continuing through the closing of the Merger.

The borrowers' obligations under the Credit Agreement and any swap obligations entered into with a lender thereunder are and will be guaranteed by the Company and each of the Company's existing and subsequently acquired or organized direct and indirect subsidiaries (other than certain immaterial subsidiaries, subsidiaries whose guarantee would result in material adverse tax consequences and subsidiaries whose guarantee is prohibited by applicable law). The borrowers' obligations under the Credit Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected security interest in (i) all tangible and intangible assets of the borrowers and the guarantors, except for certain customary excluded assets, and (ii) all of the capital stock owned by the borrowers and guarantors thereunder (limited, in the case of the stock of certain non-U.S. subsidiaries of U.S. HoldCo, to 65% of the capital stock of such subsidiaries).





**Table of Contents**

U.S. HoldCo is permitted to make voluntary prepayments of loans under the Term Loan Facility, except that (i) a specified make-whole amount would apply to any repayment or repricing prior to the second anniversary of the Closing Date, (ii) a 4% premium would apply to any repayment or repricing on or prior to the third anniversary of the Closing Date, and (iii) a 2% premium would apply to any repayment or repricing on or prior to the fourth anniversary of the Closing Date. U.S. HoldCo is required to make mandatory prepayments of loans under the Term Loan Facility (without payment of a premium) with (a) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (b) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions), and (c) net cash proceeds from issuances of debt (other than certain permitted debt).

The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. Events of default under the Credit Agreement include: (i) the failure by the borrowers to timely make payments due under the Credit Agreement; (ii) material misrepresentations or misstatements in any representation or warranty by any party when made; (iii) failure by any borrower or guarantor thereunder to comply with the covenants under the Credit Agreement and other related agreements; (iv) certain defaults under a specified amount of other indebtedness of the Company or its subsidiaries; (v) insolvency or bankruptcy-related events with respect to the Company or any of its material subsidiaries; (vi) certain undischarged judgments against the Company or any of its restricted subsidiaries; (vii) certain ERISA-related events reasonably expected to have a material adverse effect on the Company and its subsidiaries taken as a whole; (viii) certain security interests or liens under the loan documents ceasing to be, or being asserted by the Company or its restricted subsidiaries not to be, in full force and effect; and (ix) any loan document or material provision thereof ceasing to be, or any proceeding being instituted asserting that such loan document or material provision is not, in full force and effect.

**Commitment Letter**

On March 18, 2014, the Company entered into the Commitment Letter with Deerfield and certain Deerfield Funds pursuant to which the Deerfield Funds had committed to provide up to \$250,000 of senior secured loans to finance the Merger. The Company paid Deerfield a commitment fee of \$5,000 upon execution of the Commitment Letter. The \$5,000 commitment fee paid to Deerfield was capitalized as a prepaid expense and was amortized to expense through June 30, 2014. The Company allowed the Commitment Letter to expire on June 30, 2014 as a result of the execution of the Senior Secured Credit Facility.

**NOTE 16 RELATED PARTY TRANSACTIONS**

The Company entered into an amendment to the employment agreement with Dr. Nohria, one of its directors. Pursuant to the amendment to the employment agreement, Dr. Nohria's employment with Vidara was terminated, and Dr. Nohria received a \$484 lump sum payment that was contingent on his execution of a general release of claims. The Company has also entered into a consulting agreement with Dr. Nohria. Pursuant to the consulting agreement, Dr. Nohria has been retained as a consultant by the Company for a term of one year, and will be paid \$10 per month of service as a consultant.

**NOTE 17 INCOME TAXES**

The Company accounts for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the year that the change is enacted.

The following table presents the (benefit) expense for income taxes for the three and nine months ended September 30, 2014 and 2013:

	For the Three Months Ended September 30,		For the Nine Ended September 30,	
	2014	2013	2014	2013
Net loss before (benefit) expense for income taxes	\$ (979)	\$ (5,227)	\$ (235,223)	\$ (47,071)
(Benefit) expense for income taxes	(3,042)	265	(3,267)	(967)
Net income (loss)	\$ 2,063	\$ (5,492)	\$ (231,956)	\$ (46,104)



**Table of Contents**

During the three months ended September 30, 2014, the Company recorded a benefit for income taxes of \$3,042 compared to an expense for income taxes of \$265 during the three months ended September 30, 2013. During the nine months ended September 30, 2014 and 2013, the Company recorded a benefit for income taxes of \$3,267 and \$967, respectively. During the three months ended September 30, 2014, the Company released a portion of its valuation allowance as a result of the Merger. In connection with the Merger, the Company recorded additional deferred tax liabilities related to certain acquired assets, which provided a source for the realization of deferred tax assets for the Company and Vidara. Accordingly, the Company recorded a net benefit for income taxes of \$3,048 for the release of its valuation allowance during the three months ended September 30, 2014.

At September 30, 2014, the Company had a net deferred tax liability of \$4,083 primarily related to temporary differences associated with its intangible assets. During the nine months ended September 30, 2014, the Company recorded a \$214,995 loss on the derivative revaluation in connection with the increase in the fair value of the embedded derivative associated with the Convertible Senior Notes. The loss on derivative revaluation was a permanent tax difference and is not deductible for income tax reporting purposes.

**NOTE 18 SHAREHOLDERS EQUITY**

In connection with the Merger, each share of HPI's common stock issued and outstanding was converted into one ordinary share of New Horizon and each warrant to acquire HPI's common stock outstanding immediately prior to the Effective Time and not terminated as of the Effective Time was converted into a warrant to acquire, on substantially the same terms and conditions as were applicable under such warrant before the Effective Time, the number of ordinary shares of New Horizon equal to the number of shares of HPI's common stock underlying such warrant immediately prior to the Effective Time. Holdings retained ownership of 31,350,000 ordinary shares of New Horizon at the Effective Time. Upon consummation of the Merger, the security holders of HPI (excluding the holders of HPI's Convertible Senior Notes) owned approximately 74% of New Horizon and Holdings owned approximately 26% of New Horizon.

As discussed in Note 15 Debt Agreements, on September 23, 2014, the Company received 384,366 of its ordinary shares as part of the settlement of the termination of the capped call transaction associated with its Convertible Senior Notes and recorded the receipt of the ordinary shares as treasury shares.

During the nine months ended September 30, 2014, the Company issued an aggregate of 7,300,853 ordinary shares upon the cash exercise of warrants and the Company received proceeds of \$33,256 representing the aggregate exercise price for such warrants. In addition, warrants to purchase an aggregate of 983,750 ordinary shares of the Company were exercised in cashless exercises, resulting in the issuance of 547,227 ordinary shares. Included in these cashless exercises were 162,309 Series A Bridge Warrants that were exercised in cashless exercises in connection with the Merger, resulting in an aggregate issuance of 248 ordinary shares. As of September 30, 2014, there were outstanding warrants to purchase 7,825,821 ordinary shares of the Company.

During the nine months ended September 30, 2014, the Company issued an aggregate of 599,769 ordinary shares in connection with the exercise of stock options and vesting of restricted stock units and received \$1,826 in proceeds in connection with the exercise of stock options. The Company also received proceeds of \$649 upon the issuance of 264,110 ordinary shares of the Company through its employee stock purchase program during the nine months ended September 30, 2014.

**NOTE 19 EQUITY INCENTIVE PLANS****Employee Stock Purchase Plans**

In July 2010, HPI's board of directors adopted the 2011 Employee Stock Purchase Plan (the 2011 ESPP). In June 2011, HPI's stockholders approved the 2011 ESPP, and it became effective upon the signing of the underwriting agreement related to HPI's initial public offering in July 2011. HPI reserved a total of 463,352 common stock for issuance under the 2011 ESPP. The 2011 ESPP provided that an additional number of shares would automatically be added to the shares authorized for issuance under the 2011 ESPP each year on January 1, until 2021. The number of shares added each year was equal to the least of: (a) 4% of the total number of common stock outstanding on December 31 of the preceding calendar year; (b) 1,053,074 common stock; or (c) a number of common stock that could be determined each year by HPI's board of directors that was less than (a) and (b). Subject to certain limitations, HPI's employees could elect to have 1% to 15% of their compensation withheld through payroll deductions to purchase common stock under the 2011 ESPP at the end of a six-month offering period. Employees purchase common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of the six-month offering period.

**Table of Contents**

On December 5, 2013, pursuant to the terms of the 2011 ESPP, HPI's board of directors approved an increase in the number of shares available for issuance under the 2011 ESPP of 1,053,074 shares, effective January 1, 2014. As of immediately prior to the closing of the Merger, 614,657 shares had been issued and an aggregate of 1,201,769 common stock were authorized and available for future grants under the 2011 ESPP. Upon consummation of the Merger, the Company assumed the 2011 ESPP.

On May 17, 2014, HPI's board of directors adopted the Horizon Pharma Public Limited Company 2014 Employee Share Purchase Plan (the 2014 ESPP). On September 18, 2014, at a special meeting of the stockholders of HPI (the Special Meeting), HPI's stockholders approved the 2014 ESPP. Upon consummation of the Merger, the Company assumed the 2014 ESPP, which will serve as the successor to the 2011 ESPP. The 2014 ESPP is intended to qualify as an employee stock purchase plan within the meaning of section 423 of the Internal Revenue Code of 1986, as amended. The 2014 ESPP provides a means by which employees of the Company (or any eligible subsidiary) may purchase the Company's ordinary shares through payroll deductions. Generally, each regular employee (including officers) employed by the Company (or a subsidiary company if the Company's board of directors designates such company as eligible to participate) will be eligible to participate in offerings under the 2014 ESPP. At the effective time of the 2014 ESPP, 10,201,769 ordinary shares were available for purchase under such plan, which number consisted of 9,000,000 ordinary shares of the Company, plus the 1,201,769 shares remaining available for issuance in the share reserve of the 2011 ESPP as of immediately prior to the effective time of the Merger. The Company's board of directors may suspend or terminate the 2014 ESPP at any time.

**Stock-Based Compensation Plans**

In October 2005, HPI adopted the 2005 Stock Plan (the 2005 Plan). The 2005 Plan provided for the granting of stock options to employees and consultants of HPI. Options granted under the 2005 Plan were either incentive stock options or nonqualified stock options. Upon the signing of the underwriting agreement related to HPI's initial public offering, on July 28, 2011, no further option grants were made under the 2005 Plan. As of July 28, 2011, the 460,842 common stock reserved for future issuance and the 1,304,713 common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan were transferred to the 2011 Equity Incentive Plan (the 2011 EIP), as described below. All stock options granted under the 2005 Plan prior to July 28, 2011 continue to be governed by the terms of the 2005 Plan. Upon consummation of the Merger, the Company assumed the 2005 Plan.

In July 2010, HPI's board of directors adopted the 2011 EIP. In June 2011, HPI's stockholders approved the 2011 EIP, and it became effective upon the signing of the underwriting agreement related to HPI's initial public offering on July 28, 2011. The 2011 EIP had an initial reserve of 3,366,228 common stock, including 460,842 common stock previously reserved for future issuance under the 2005 Plan, 1,304,713 common stock reserved for future issuance upon the exercise of options outstanding under the 2005 Plan as of the 2011 EIP's effective date and 1,600,673 new common stock reserved. The 2011 EIP provided that an additional number of shares would automatically be added to the shares authorized for issuance each year on January 1, until 2021. The number of shares added each year were equal to the least of: (a) 5% of the total number of common stock outstanding on December 31 of the preceding calendar year; (b) 1,474,304 common stock; or (c) a number of common stock that could be determined each year by HPI's board of directors that was less than (a) and (b). On December 5, 2013, pursuant to the terms of HPI's 2011 EIP, HPI's board of directors approved an increase in the number of shares available for issuance under the 2011 EIP of 1,474,304 shares, effective January 1, 2014. On November 7, 2013, November 16, 2013 and March 3, 2014, HPI's board of directors approved amendments to the 2011 EIP to reserve an additional 200,000 shares, 800,000 shares and 730,000 shares, respectively, of HPI's common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of HPI (or following a bona fide period of non-employment with HPI), as an inducement material to the individual's entry into employment with HPI within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules (Rule 5635(c)(4)). On January 10, 2014, HPI's board of directors approved an amendment to the 2011 EIP to increase the number of shares available for issuance under the 2011 EIP by 703,400 shares (the January 2014 amendment), with such increase to the number of shares available for issuance under the 2011 EIP subject to stockholder approval of the January 2014 amendment.

**Table of Contents**

On May 17, 2014, HPI's board of directors approved an amendment to the 2011 EIP to among other things: increase the aggregate number of shares authorized for issuance under the 2011 EIP by an additional 10,000,000 shares; eliminate the annual evergreen provision and require stockholder approval for the issuance of additional shares; and provide that shares reserved as part of the inducement pool under Rule 5635(c)(4) may be used for grants to any eligible participant under the 2011 EIP. On June 27, 2014, HPI's stockholders approved the amendment to the 2011 EIP. As of immediately prior to the closing of the Merger, there were 7,341,996 shares available for future grants under the 2011 EIP. Upon consummation of the Merger, the Company assumed the 2011 EIP.

On May 17, 2014, HPI's board of directors adopted the Horizon Pharma Public Limited Company 2014 Equity Incentive Plan (the 2014 EIP) and the Horizon Pharma Public Limited Company 2014 Non-Employee Equity Plan (the 2014 Non-Employee Equity Plan). At the Special Meeting, HPI's stockholders approved the 2014 EIP and 2014 Non-Employee Equity Plan. Upon consummation of the Merger, the Company assumed the 2014 EIP and 2014 Non-Employee Equity Plan, which will serve as successors to the 2011 EIP.

The 2014 EIP provides for the grant of incentive and nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards, and performance awards that may be settled in cash, shares or other property to the employees of the Company (or a subsidiary company). The number of ordinary shares of the Company that are authorized for issuance under the 2014 Plan will be no more than 22,052,130, which number consists of (i) 15,500,000 ordinary shares of the Company; plus (ii) the number of shares available for issuance pursuant to the grant of future awards under the 2011 EIP; plus (iii) any shares subject to outstanding stock awards granted under the 2011 EIP and the 2005 Plan that expire or terminate for any reason prior to exercise or settlement or are forfeited, redeemed or repurchased because of the failure to meet a contingency or condition required to vest such shares; less (iv) 10,000,000 shares, which is the additional number of shares which were previously approved as an increase to the share reserve of the 2011 EIP. The Company's board of directors has authority to suspend or terminate the 2014 EIP at any time.

The 2014 Non-Employee Equity Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of stock awards that may be settled in cash, shares or other property to the non-employee directors and consultants of the Company (or a subsidiary company). The total number of ordinary shares of the Company authorized for issuance under the 2014 Non-Employee Equity Plan is 2,500,000. The Company's board of directors has authority to suspend or terminate the 2014 Non-Employee Equity Plan at any time.

**Stock Option Plans**

The following table summarizes stock option activity during the nine months ended September 30, 2014:

	<b>Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding as of December 31, 2013	4,411,080	\$ 6.47
Granted	3,065,686	\$ 10.20
Exercised	(327,305)	\$ 5.62
Forfeited	(431,174)	\$ 5.64
Outstanding as of September 30, 2014	6,718,287	\$ 8.27
Exercisable as of September 30, 2014	2,812,548	\$ 8.65

**Table of Contents**

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The determination of the fair value of each stock option is affected by the Company's stock price on the date of grant, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company's expected stock price volatility over the expected life of the awards and actual and projected stock option exercise behavior. The weighted average fair value per share of stock option awards granted during the nine months ended September 30, 2014 and 2013, and assumptions used to value stock options, are as follows:

	<b>For the Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
Dividend yield		
Risk-free interest rate	1.92%	1.1%
Weighted average volatility	83.06%	87.7%
Expected life (in years)	6.02	5.98
Weighted average grant date fair value per share of options granted	\$ 8.77	\$ 2.39

*Dividend yields*

The Company has never paid dividends and does not anticipate paying any dividends in the near future.

*Risk-Free Interest Rate*

The Company determined the risk-free interest rate by using a weighted average assumption equivalent to the expected term based on the U.S. Treasury constant maturity rate as of the date of grant.

*Volatility*

The Company used an average historical stock price volatility of comparable companies to be representative of future stock price volatility, as the Company did not have sufficient trading history for its common stock.

*Expected Term*

Given the Company's limited historical exercise behavior, the expected term of options granted was determined using the simplified method since the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Under this approach, the expected term is presumed to be the average of the vesting term and the contractual life of the option.

*Forfeitures*

During the nine months ended September 30, 2013, the Company utilized a forfeiture rate of 5% for estimating the forfeitures of stock options granted. During the nine months ended September 30, 2014, the Company reassessed its forfeiture rate based on actual historical experience and subsequently utilized a forfeiture rate that ranges from 5% to 15% based on the stratification of various employee grant categories.

*Restricted Stock Units*

The following table summarizes restricted stock unit activity during the nine months ended September 30, 2014:

	<b>Number of Units</b>	<b>Weighted Average Grant-Date Fair Value Per Units</b>
Outstanding as of December 31, 2013	833,001	\$ 2.86
Granted	1,139,022	\$ 10.28

## Edgar Filing: Horizon Pharma plc - Form 10-Q

Vested	(285,691)	\$	3.70
Forfeited	(48,933)	\$	2.95
Outstanding as of September 30, 2014	1,637,399	\$	7.87

**Table of Contents**

The following table summarizes share-based compensation expense included in the Company's condensed consolidated statements of comprehensive loss for the nine months ended September 30, 2014 and 2013:

	For the Nine Months Ended September 30,	
	2014	2013
<b>Stock-based compensation expense:</b>		
Research and development	\$ 1,152	\$ 700
Sales and marketing	3,278	1,000
General and administrative	5,681	1,506
<b>Total stock-based compensation expense</b>	<b>\$ 10,111</b>	<b>\$ 3,206</b>

The Company estimates that, as of September 30, 2014, pre-tax compensation expense was \$35,502 for all unvested stock-based awards, including both stock options and restricted stock units that will be recognized through the fourth quarter of 2017. The Company expects to satisfy the exercise of stock options and future distribution of shares of restricted stock by issuing new ordinary shares which have been reserved under the 2014 EIP.

**NOTE 20 SUBSEQUENT EVENTS**

On October 17, 2014, the Company announced the acquisition of the U.S. rights to PENNSAID 2% from Nuvo for a one-time payment of \$45,000 in cash. PENNSAID 2% is approved in the United States for the treatment of the pain of OA of the knee(s). As part of the acquisition, the Company entered into an eight-year exclusive supply agreement with Nuvo and the Company expects to begin selling PENNSAID 2% in early January 2015. The Company plans to expand its primary care sales force of 260 representatives by approximately 75 additional representatives and include PENNSAID 2% in the PME specialty pharmacy program.

On October 23, 2014 and October 27, 2014, the Company entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes. Under the conversion agreements, the holders agreed to convert an aggregate principal amount of \$69,434 of Convertible Senior Notes held by them and the Company agreed to settle such conversions by issuing 12,944,350 ordinary shares. In addition, pursuant to the conversion agreements, the Company made an aggregate cash payment of \$14,614 to the holders for additional exchange consideration and accrued and unpaid interest. The transactions closed on or before October 31, 2014. Immediately following the conversions of the Convertible Senior Notes contemplated by the conversion agreements, \$80,566 in aggregate principal amount of the Convertible Senior Notes remained outstanding.

On November 4, 2014, the Company entered into a lease agreement with John Ronan and Castle Cove Property Developments Limited for lease a 10,266 square feet of space in a facility located in Dublin, Ireland through the Company's wholly-owned subsidiary, Horizon Pharma Services Limited. The Company is also a direct party to the lease as a guarantor. The lease is for a term of 15 years, commencing on November 4, 2014. For the first five years of the Lease, the minimum rent due is 483 (Euro) per year and is payable in equal quarterly payments. On November 5, 2019 and each fifth anniversary thereafter, the rental rate will be set to a current market rate, as determined by the procedures set forth in the lease. The Company has the right to terminate the lease after ten years by giving at least nine months prior notice to the landlord.

None of the foregoing subsequent events had an impact on the Company's statement of operations for the quarter ended September 30, 2014 or the balance sheet as of September 30, 2014.



**Table of Contents****Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and the related notes that appear elsewhere in this report. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties which are subject to safe harbors under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements include, but are not limited to, statements concerning our strategy and other aspects of our future operations, future financial position, future revenues, projected costs, expectations regarding demand and acceptance for our products, growth opportunities and trends in the market in which we operate, prospects, plans and objectives of management and statements related to the anticipated effects of the merger involving Horizon Pharma, Inc. and Vidara Therapeutics International plc. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, Risk Factors in this report and in our other filings with the Securities and Exchange Commission, or SEC. We do not assume any obligation to update any forward-looking statements.*

*(Dollars are presented in thousands except share data or unless otherwise stated)*

**Merger with Vidara**

On September 19, 2014, the businesses of Horizon Pharma, Inc., or HPI, and Vidara Therapeutics International Public Limited Company, or Vidara, were combined in a merger transaction, or the Merger, accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with HPI treated as the acquiring company in the Merger for accounting purposes. As part of the Merger, a wholly-owned subsidiary of Vidara merged with and into HPI, with HPI surviving the Merger as a wholly-owned subsidiary of Vidara. Prior to the Merger, Vidara changed its name to Horizon Pharma plc, or New Horizon. Upon the consummation of the Merger, the historical financial statements of HPI became our historical financial statements. Accordingly, the historical financial statements of HPI are included in the comparative prior periods.

Unless otherwise indicated or the context otherwise requires, references to the Company, New Horizon, we, us and our refer to Horizon Pharma plc and its consolidated subsidiaries, including its predecessor, HPI. All references to Vidara or the acquired company are references to Horizon Pharma plc (f/k/a Vidara Therapeutics International Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Merger on September 19, 2014. The disclosures in this report relating to the pre-Merger business of Horizon Pharma plc, unless noted as being the business of Vidara prior to the Merger, pertain to the business of HPI prior to the Merger.

**OUR BUSINESS**

We are a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated products that address unmet medical needs. We market a portfolio of products in arthritis, inflammation and orphan diseases. Our U.S. marketed products are ACTIMMUNE® (interferon gamma-1b), DUEXIS® (ibuprofen/famotidine), RAYOS® (prednisone) delayed-release tablets and VIMOVO® (naproxen/esomeprazole). We developed DUEXIS and RAYOS/LODOTRA, acquired the U.S. rights to VIMOVO from AstraZeneca AB (AstraZeneca) in November 2013 and acquired the U.S. rights to ACTIMMUNE as a result of the Merger. We market our products in the United States through our field sales force of approximately 310 representatives. Our strategy is to develop, acquire or in-license additional innovative medicines or acquire companies, such as the recently-completed Merger with Vidara.

On April 23, 2011, the U.S. Food and Drug Administration, or FDA, approved DUEXIS, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and famotidine in a single pill. DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis, or RA, osteoarthritis, or OA, and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for these indications. We began detailing DUEXIS to physicians in December 2011. In June 2012, we licensed DUEXIS rights in Latin America to Grünenthal S.A., a private company focused on the promotion of pain products.

Our second approved product in the United States, RAYOS, known as LODOTRA outside the United States, is a proprietary delayed-release formulation of low-dose prednisone, first approved in Europe in March 2009, for the treatment of moderate to severe, active RA in adults, particularly when accompanied by morning stiffness. On July 26, 2012, the FDA approved RAYOS for the treatment of RA, polymyalgia rheumatica, or PMR, psoriatic arthritis, ankylosing spondylitis, or AS, asthma and chronic obstructive pulmonary disease and a number of other conditions. We are focusing our promotion of RAYOS in the United States on rheumatology indications, including RA and PMR. We began

## Edgar Filing: Horizon Pharma plc - Form 10-Q

detailing RAYOS to a subset of U.S. rheumatologists in December 2012 and began the full launch in late January 2013 to the majority of U.S. rheumatologists and key primary care physicians. LODOTRA is currently marketed outside the United States by our distribution partner, Mundipharma International Corporation Limited, or Mundipharma.

**Table of Contents**

On November 18, 2013, we entered into agreements with AstraZeneca pursuant to which we acquired from AstraZeneca and its affiliates certain intellectual property and other assets, and assumed from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO, and obtained rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with non-steroidal anti-inflammatory drugs, or NSAIDs, in the United States. VIMOVO (naproxen/esomeprazole magnesium) is a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core. VIMOVO was originally developed by Pozen Inc., or Pozen, together with AstraZeneca pursuant to an exclusive global collaboration and license agreement under which AstraZeneca and Pozen agreed to co-develop VIMOVO and AstraZeneca obtained exclusive rights to commercialize VIMOVO worldwide. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of OA, RA, and AS and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

Under the asset purchase agreement with AstraZeneca, we acquired certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the investigational new drug application and new drug application for VIMOVO in the United States, AstraZeneca's interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. In addition, AstraZeneca assigned to us its amended and restated collaboration and license agreement for the United States with Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States.

In December 2013, as a result of the acquisition of the U.S. rights to VIMOVO, we recognized revenues under our transition agreement with AstraZeneca. We announced the availability of Horizon-labeled VIMOVO on January 2, 2014, at which time we also began promotion with our primary care sales force.

On March 18, 2014, HPI, Vidara Therapeutics Holdings LLC, a Delaware limited liability company, or Holdings, Vidara, Hamilton Holdings (USA), Inc., a Delaware corporation and an indirect wholly-owned subsidiary of Vidara, or U.S. HoldCo, and Hamilton Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of U.S. HoldCo, or Merger Sub, entered into a Transaction Agreement and Plan of Merger, or the Merger Agreement. The Merger Agreement provided for the merger of Merger Sub with and into HPI, with HPI continuing as the surviving corporation and as a wholly-owned, indirect subsidiary of Vidara, with Vidara converting to a public limited company and changing its name to Horizon Pharma plc. As a result of the Merger, we are organized under the laws of Ireland. Upon consummation of the Merger, or the Closing, HPI's security holders (excluding the holders of the HPI convertible notes) owned approximately 74% of New Horizon and Holdings owned approximately 26% of New Horizon. At the Closing, New Horizon made a cash payment of \$210,871 to Holdings and \$2,750 to Citibank N.A. as escrow agent under an escrow agreement associated with the Merger.

As a result of the Merger, we began marketing ACTIMMUNE®, a bioengineered form of interferon gamma-1b, a protein that acts as a biologic response modifier, in the United States. ACTIMMUNE is approved by the FDA for use in children and adults with chronic granulomatous disease, or CGD, and severe, malignant osteopetrosis, or SMO. ACTIMMUNE is indicated for reducing the frequency and severity of serious infections associated with CGD and for delaying time to disease progression in patients with SMO.

The New Horizon ordinary shares issued to HPI's stockholders were registered with the SEC and are listed on NASDAQ. In connection with the Merger, on June 17, 2014, HPI entered into a \$300,000 five-year senior secured credit facility, or Senior Secured Credit Facility, with certain lenders and Citibank, N.A., as administrative agent and collateral agent. HPI used the proceeds of the Senior Secured Credit Facility to provide the cash payment of \$213,621 for Vidara and to pay certain transaction related expenses, and the Company is using the balance for general corporate purposes.

On October 17, 2014, we announced the acquisition of the U.S. rights to PENNSAID® (diclofenac sodium topical solution) 2% w/w ( PENNSAID 2% ) from Nuvo Research Inc. ( Nuvo ) for a one-time payment of \$45,000 in cash. PENNSAID 2% is approved in the U.S. for the treatment of the pain of OA of the knee(s). As part of the acquisition, we entered into an eight-year exclusive supply agreement with Nuvo and the Company expects to begin selling PENNSAID 2% in early January 2015. We plan to expand its primary care sales force of 250 representatives by approximately 75 additional representatives and include PENNSAID 2% in its *Prescriptions Made Easy* ( PME ) specialty pharmacy program.

**Table of Contents****RESULTS OF OPERATIONS****Comparison of Three Months Ended September 30, 2014 and 2013**

The summary of selected financial data table below should be referenced in connection with a review of the following discussion of our results of operations for the three months ended September 30, 2014, compared to the three months ended September 30, 2013.

	<b>Three Months Ended September 30,</b>		<b>Increase / (Decrease)</b>
	<b>2014</b>	<b>2013</b>	
Net sales	75,126	24,112	51,014
Cost of goods sold	13,644	3,207	10,437
<b>Gross profit</b>	<b>61,482</b>	<b>20,905</b>	<b>40,577</b>
Operating expenses			
Research and development	4,223	2,154	2,069
Sales and marketing	31,111	15,621	15,490
General and administrative	38,109	5,874	32,235
Total operating expenses	73,443	23,649	49,794
<b>Operating loss</b>	<b>(11,961)</b>	<b>(2,744)</b>	<b>(9,217)</b>
Other income (expense), net:			
Interest expense, net	(5,194)	(3,601)	1,593
Foreign exchange (loss) gain	(2,754)	1,118	3,872
Bargain purchase gain	22,171		(22,171)
Other expense	(3,241)		3,241
<b>Total other income (expense), net</b>	<b>10,982</b>	<b>(2,483)</b>	<b>(13,465)</b>
Loss before (benefit) expense for income taxes	(979)	(5,227)	(4,248)
<b>(Benefit) expense for income taxes</b>	<b>(3,042)</b>	<b>265</b>	<b>3,307</b>
<b>Net income (loss)</b>	<b>\$ 2,063</b>	<b>\$ (5,492)</b>	<b>\$ (7,555)</b>

*Net sales.* During the three months ended September 30, 2014, net sales were \$75,126, an increase of \$51,014 compared to net sales of \$24,112 during the three months ended September 30, 2013.

DUEXIS net sales during the three months ended September 30, 2014 were \$22,753 compared to net sales of \$21,513 during the three months ended September 30, 2013. The increase in DUEXIS net sales during the three months ended September 30, 2014 compared to the prior year period was primarily the result of increased prescription volume driven by our expanded field sales organization, partially offset by increased sales discounts and allowances.

VIMOVO net sales during the three months ended September 30, 2014 were \$43,206. On November 26, 2013, we began promotion of VIMOVO with our rheumatology sales force and began commercialization through our primary care sales force on January 2, 2014.

RAYOS net sales were \$5,651 during the three months ended September 30, 2014 compared to net sales of \$1,871 during the three months ended September 30, 2013. The increase in RAYOS net sales during the three months ended September 30, 2014 compared to the prior year period was primarily attributable to increased volume driven by the expansion of our sales force focused on RAYOS and product price increases implemented during the course of 2013 and 2014.

## Edgar Filing: Horizon Pharma plc - Form 10-Q

ACTIMMUNE net sales were \$2,707 during the three months ended September 30, 2014, representing sales during the period following the Merger with Vidara on September 19, 2014.

LODOTRA net sales were \$808 during the three months ended September 30, 2014 compared to net sales of \$754 during the three months ended September 30, 2013. The increase in LODOTRA net sales was the result of the timing of product shipments to our European distribution partner, Mundipharma. LODOTRA sales to Mundipharma occur at the time we ship product based on Mundipharma's estimated requirements. Accordingly, LODOTRA sales are not linear or directly tied to Mundipharma sales to the market and can therefore fluctuate significantly from quarter to quarter.

**Table of Contents**

*Cost of Goods Sold.* Cost of goods sold increased \$10,437 to \$13,644 during the three months ended September 30, 2014, from \$3,207 during the three months ended September 30, 2013. The increase in cost of goods sold was primarily due to higher intangible amortization expense of \$4,732, an increase in royalty accretion expense of \$2,664 and higher product costs of \$3,041. During the three months ended September 30, 2014, intangible amortization expense increased \$4,732 due to a \$3,303 increase in intangible amortization expense related to our Vimovo intellectual property acquired in November 2013 and \$1,463 in intangible amortization expense incurred in connection with developed technology for ACTIMMUNE acquired as a result the Merger with Vidara in September 2014. Royalty accretion increased \$2,664 primarily as a result of accretion of accrued royalties related to VIMOVO. Additionally, product costs increased \$3,041 during the three months ended September 30, 2014 compared to the prior year period due to higher product shipments along with the recognition in cost of goods sold of \$1,540 of step-up inventory costs related to ACTUMMUNE inventory sold during the current period.

*Research and Development Expenses.* Research and development expenses increased \$2,069 to \$4,223 during the three months ended September 30, 2014, from \$2,154 during the three months ended September 30, 2013. The increase in research and development expenses during the third quarter of 2014 was primarily associated with \$1,278 in higher salaries and benefits expense, a \$271 increase in consulting fees and \$193 in increased clinical expenses.

*Sales and Marketing Expenses.* Sales and marketing expenses increased \$15,490 to \$31,111 during the three months ended September 30, 2014, from \$15,621 during the three months ended September 30, 2013. The increase in sales and marketing expenses was primarily attributable to an increase of \$8,993 in salaries and benefits expenses associated with increased staffing of our field sales force, \$4,980 in higher marketing and commercialization expenses primarily related to VIMOVO, \$1,112 in higher facility expenses and the inclusion of \$579 in sales and marketing expenses related to ACTIMMUNE.

*General and Administrative Expenses.* General and administrative expenses increased \$32,235 to \$38,109 during the three months ended September 30, 2014, from \$5,874 during the three months ended September 30, 2013. The increase in general and administrative expenses was primarily due to \$28,255 of transaction expenses related to the Merger with Vidara, including investment banking, legal and consulting fees, as well as increases for additional staff and other costs related to the growth of the business.

*Interest Expense, Net.* Interest expense, net increased \$1,593 to \$5,194 during the three months ended September 30, 2014, from \$3,601 during the three months ended September 30, 2013. The increase in interest expense, net during the three months ended September 30, 2014 was primarily attributable to higher debt discount expenses of \$1,119 and interest expense of \$474 as a result of higher debt discount expenses incurred in connection with our 5.00% Convertible Senior Notes due 2018 and borrowing costs under our five-year Senior Secured Credit Facility.

*Foreign Exchange Loss.* During the three months ended September 30, 2014, we recorded a foreign exchange loss of \$2,754 compared to a foreign exchange gain of \$1,118 during the three months ended September 30, 2013. The foreign exchange loss during the third quarter of 2014 was primarily attributable to a weakening of the Euro against the U.S. dollar during the three months ended September 30, 2014. Our Horizon Pharma AG subsidiary intercompany balances and intercompany transactions are denominated in U.S. dollars. A weakening in the value of the Euro during the three months ended September 30, 2014 resulted in the foreign exchange loss during the current period.

*Bargain Purchase Gain.* During the three months ended September 30, 2014, we recorded a bargain purchase gain of \$22,171 in connection with our merger with Vidara, representing the excess of the estimated fair values of net assets acquired over the acquisition consideration paid.

*Other Expense.* Other expense during the three months ended September 30, 2014 totaled \$3,231 representing commitment fees incurred prior to the funding of the Senior Secured Credit Facility on September 19, 2014.

*Income Tax Expense (Benefit).* During the three months ended September 30, 2014, we recorded a benefit for income taxes of \$3,042 compared to an expense for income taxes of \$265 during the three months ended September 30, 2013. The increase in income tax benefit during the three months ended September 30, 2014 was attributable to a reduction in our deferred tax asset positions during the current quarter. The inclusion of additional deferred tax liabilities as a result of our merger with Vidara resulted in our ability to reduce our existing deferred tax valuation allowance, which correspondingly resulted in our ability to record an additional income tax benefit of \$3,048.

*Net Income (Loss).* During the three months ended September 30, 2014, we recorded net income of \$2,063 compared to a net loss of \$5,492 during the three months ended September 30, 2013.

**Table of Contents****Comparison of Nine Months Ended September 30, 2014 and 2013**

The summary of selected financial data table below should be referenced in connection with a review of the following discussion of our results of operations for the nine months ended September 30, 2014, compared to the nine months ended September 30, 2013.

	<b>Nine Months Ended September 30,</b>		<b>Increase / (Decrease)</b>
	<b>2014</b>	<b>2013</b>	
Net sales	193,114	43,936	149,178
Cost of goods sold	46,073	9,370	36,703
<b>Gross profit</b>	<b>147,041</b>	<b>34,566</b>	<b>112,475</b>
Operating expenses			
Research and development	10,601	7,185	3,416
Sales and marketing	86,932	48,475	38,457
General and administrative	66,982	15,998	50,984
Total operating expenses	164,515	71,658	92,857
Operating loss	(17,474)	(37,092)	19,618
Other income (expense), net:			
Interest expense, net	(13,608)	(10,646)	2,962
Foreign exchange loss	(3,076)	667	3,743
Loss on derivative fair value	(214,995)		214,995
Bargain purchase gain	22,171		(22,171)
Other expense	(8,241)		8,241
Total other expense, net	(217,749)	(9,979)	207,770
Loss before benefit for income taxes	(235,223)	(47,071)	188,152
Benefit for income taxes	(3,267)	(967)	2,300
<b>Net loss</b>	<b>\$ (231,956)</b>	<b>\$ (46,104)</b>	<b>\$ 185,852</b>

*Net sales.* During the nine months ended September 30, 2014, net sales were \$193,114 compared to net sales of \$43,936 during the nine months ended September 30, 2013.

DUEXIS net sales during the nine months ended September 30, 2014 were \$54,465 compared to net sales of \$35,881 during the nine months ended September 30, 2013. The increase in DUEXIS net sales during the nine months ended September 30, 2014 compared to the prior year period was primarily the result of prescription volume growth driven by expansion of the field sales organization, partially offset by increased sales discounts and allowances.

VIMOVO net sales during the nine months ended September 30, 2014 were \$119,622. On November 26, 2013, we began promotion of VIMOVO with our rheumatology sales force and began commercialization through our primary care sales force on January 2, 2014.

RAYOS net sales were \$12,897 during the nine months ended September 30, 2014 compared to net sales of \$2,719 during the nine months ended September 30, 2013. The increase in RAYOS net sales during the nine months ended September 30, 2014 compared to the prior year period was primarily attributable to increased volume driven by the expansion of our sales force focused on RAYOS and product price increases implemented during the course of 2013 and 2014.

ACTIMMUNE net sales were \$2,707 during the nine months ended September 30, 2014, representing sales during the period following the Merger with Vidara on September 19, 2014.

## Edgar Filing: Horizon Pharma plc - Form 10-Q

LODOTRA net sales were \$3,422 during the nine months ended September 30, 2014 compared to net sales of \$5,334 during the nine months ended September 30, 2013. The decrease in LODOTRA net sales was the result of the timing of product shipments to our European distribution partner, Mundipharma. LODOTRA sales to Mundipharma occur at the time we ship product based on Mundipharma's estimated requirements. Accordingly, LODOTRA sales are not linear or directly tied to Mundipharma sales to the market and can therefore fluctuate significantly from quarter to quarter.



**Table of Contents**

*Cost of Goods Sold.* Cost of goods sold increased \$36,703 to \$46,073 during the nine months ended September 30, 2014, from \$9,370 during the nine months ended September 30, 2013. The increase in cost of goods sold was primarily due to a \$13,033 charge for a contingent VIMOVO royalty liability, increase in intangible amortization expense of \$11,491, increase in product costs of \$6,563 and higher royalty accretion costs of \$5,617 during the nine months ended September 30, 2014. The increase in product costs was due to higher product shipments of DUEXIS and VIMOVO.

At the time of our acquisition of the U.S. rights to VIMOVO from AstraZeneca in the fourth quarter of 2013, we estimated the fair value of contingent royalties payable to Pozen using an income approach under the discounted cash flow method, which included revenue projections and other assumptions we made to determine the fair value. If we were to significantly overperform or underperform against our original revenue projections or it became necessary to make changes to our assumptions as a result of a triggering event, we would be required to reassess the fair value of the contingent royalties payable to Pozen. Any adjustments to fair value would be recorded in the period such adjustment was made as either an increase or decrease to royalties payable, with a corresponding increase or decrease in cost of goods sold, in accordance with our established accounting policies, and would impact the reported operating results in the period the adjustment was made. During the second quarter of 2014, based on higher sales of VIMOVO during the six months ended June 30, 2014 versus our original expectations and our adjusted expectations for future VIMOVO sales, we recorded a charge of \$13,033 to cost of goods sold to increase the amount of the contingent royalty liability to reflect the updated estimates.

Intangible amortization increased \$11,491 during the nine months ended September 30, 2014 compared to the prior year period due to \$9,908 in amortization related to our VIMOVO intellectual property and \$1,463 in intangible amortization expense incurred in connection with developed technology for ACTIMMUNE acquired as a result of the Merger with Vidara.

*Research and Development Expenses.* Research and development expenses increased \$3,416 to \$10,601 during the nine months ended September 30, 2014, from \$7,185 during the nine months ended September 30, 2013. The increase in research and development expenses during the nine months ended September 30, 2014 was primarily associated with \$1,675 in higher salaries and benefits expense, \$639 in higher consulting costs and \$651 in increased clinical expenses.

*Sales and Marketing Expenses.* Sales and marketing expenses increased \$38,457 to \$86,932 during the nine months ended September 30, 2014, from \$48,475 during the nine months ended September 30, 2013. The increase in sales and marketing expenses was primarily attributable to an increase of \$25,017 in salaries and benefits expenses associated with increased staffing of our field sales force, \$9,443 in higher marketing and commercialization expenses primarily related to VIMOVO and \$2,579 in higher facility expenses.

*General and Administrative Expenses.* General and administrative expenses increased \$50,984 to \$66,982 during the nine months ended September 30, 2014, from \$15,998 during the nine months ended September 30, 2013. The increase in general and administrative expenses was primarily due to \$37,429 of transaction expenses related to the Merger with Vidara, \$6,361 related to higher salaries and benefits expense as a result of increased staffing of our administrative functions, \$3,133 in higher facilities expenses and a \$855 increase in legal fees associated with intellectual property related matters during the nine months ended September 30, 2014.

*Interest Expense, Net.* Interest expense, net increased \$2,962 to \$13,608 during the nine months ended September 30, 2014, from \$10,646 during the nine months ended September 30, 2013. The increase in interest expense, net was primarily attributable to higher debt discount expenses of \$4,039, partially offset by \$1,077 in lower interest expense due to lower borrowing costs under our Convertible Senior Notes and Senior Secured Credit Facility during the nine months ended September 30, 2014 compared to our borrowing costs during the nine months ended September 30, 2013 under our prior senior secured loan facility.

*Foreign Exchange Loss.* During the nine months ended September 30, 2014, we reported a foreign exchange loss of \$3,076 compared to a foreign exchange gain of \$667 during the nine months ended September 30, 2013. The foreign exchange loss during the third quarter of 2014 was primarily attributable to a 9% weakening of the Euro against the U.S. dollar during the nine months ended September 30, 2014. Our Horizon Pharma AG subsidiary intercompany balances and intercompany transactions are denominated in U.S. dollars. A weakening in the value of the Euro during the nine months ended September 30, 2014 resulted in the foreign loss compared to the prior year period.

*Loss on Derivative Revaluation.* During the nine months ended September 30, 2014, we recorded a \$214,995 non-cash charge related to the increase in the fair value of the embedded derivative associated with our Convertible Senior Notes. The increase in loss on the derivative revaluation was primarily due to an increase in the market value of our common stock during the period from January 1, 2014 through June 27, 2014, the date HPI's stockholders approved the issuance of common equity in excess of 13,164,951 shares upon conversion of the Convertible Senior Notes. The loss on derivative revaluation was a permanent tax difference and was not deductible for income tax reporting purposes.



---

## **Table of Contents**

*Bargain Purchase Gain.* During the nine months ended September 30, 2014, we recorded a bargain purchase gain of \$22,171 in connection with the Merger with Vidara, representing the excess of the estimated fair values of net assets acquired over the acquisition consideration paid.

*Other Expense.* Other expense during the nine months ended September 30, 2014 totaled \$8,241 representing commitment fees incurred on the bridge financing in place prior to executing the Senior Secured Credit Facility in June along with commitment fees incurred on the Senior Secured Credit Facility prior to its funding on September 19, 2014.

*Income Tax Expense (Benefit).* During the nine months ended September 30, 2014 and 2013, we recorded a benefit for income taxes of \$3,267 and \$967, respectively. The increase in income tax benefit during the nine months ended September 30, 2014 was attributable to a deferred tax asset valuation adjustment of \$3,048 recorded during the third quarter of 2014. The inclusion of additional deferred tax liabilities as a result of our merger with Vidara resulted in our ability to reduce our existing deferred tax valuation allowance, which correspondingly resulted in our ability to record an additional income tax benefit of \$3,048.

*Net Loss.* Net loss increased \$185,852 to \$231,956 during the nine months ended September 30, 2014, from \$46,104 during the nine months ended September 30, 2013, primarily as a result of the loss on derivative revaluation during the nine months ended September 30, 2014.

### **Summary of Critical Accounting Policies**

The methods, estimates and judgments that we use in applying our critical accounting policies have a significant impact on the results that we report in our financial statements. Some of our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates regarding matters that are inherently uncertain.

We have identified the accounting policies and estimates listed below as those that we believe require management's most subjective and complex judgments in estimating the effect of inherent uncertainties. This section should also be read in conjunction with Note 2, Summary of Significant Accounting Policies, in the notes to our condensed consolidated financial statements included in this report, which includes a discussion of these and other significant accounting policies.

#### *Revenue Recognition*

Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured. Some of our agreements contain multiple elements and in accordance with these agreements, we may be eligible for upfront license fees, marketing or commercial milestones and payment for product deliveries.

#### *Revenue from Product Deliveries*

We recognize revenue from the delivery of our products when delivery has occurred, title has transferred, the selling price is fixed or determinable, the right of return no longer exists (which is the earlier of product being dispensed through patient prescriptions or the expiration of the right of return) or product returns can be reasonably estimated, collectability is reasonably assured and we have no further performance obligations. Due to our ability to reasonably estimate and determine allowances for product returns, rebates and discounts based on our own internal data for DUEXIS and RAYOS or data relating to prior sales of VIMOVO and ACTIMMUNE received in connection with the acquisition of those products, we recognize revenue at the point of sale to wholesale pharmaceutical distributors and retail chains for all currently distributed products.

#### *Revenue from Upfront License Fees*

We recognize revenues from the receipt of non-refundable, upfront license fees. In situations where the licensee is able to obtain stand-alone value from the license and no further performance obligations exist on our part, revenues are recognized on the earlier of when payments are received or collection is reasonably assured. Where continuing involvement by us is required in the form of technology transfer, product manufacturing or technical support, revenues are deferred and recognized over the term of the agreement.

#### *Revenue from Milestone Receipts*

Milestone payments are recognized as revenue based on achievement of the associated milestones, as defined in the relevant agreements. Revenue from a milestone achievement is recognized when earned, as evidenced by acknowledgment from our partner, provided that (1) the

## Edgar Filing: Horizon Pharma plc - Form 10-Q

milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (2) the milestone represents the culmination of an earnings process and (3) the milestone payment is non-refundable. If any of these criteria are not met, revenue from the milestone achievement is recognized over the remaining minimum period of our performance obligations under the agreement.

## **Table of Contents**

### *Contractual Allowances*

#### *Product Sales Discounts and Allowances*

We record allowances for product returns, rebates and discounts at the time of sale to wholesale pharmaceutical distributors and national and regional retail chains. We are also required to make significant judgments and estimates in determining some of these allowances. If actual results differ from our estimates, we will be required to make adjustments to these allowances in the future.

#### *Product Launch Discounts*

We have offered additional discounts to wholesale distributors for product purchased at the time of product launch. We have recorded these discounts as an allowance against accounts receivable and a reduction of revenue when orders were placed.

#### *Customer Rebates*

We participate in certain commercial rebate programs. Under these rebate programs, we pay a rebate to the commercial entity or third-party administrator of the program. We accrue estimated rebates based on contract prices, estimated percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel and record the rebate as a reduction of revenue.

#### *Distribution Service Fees*

We include distribution service fees paid to our wholesalers for distribution and inventory management services as a reduction to revenue. The estimates are based on contractually determined fees, typically as a percentage of revenue.

#### *Co-Pay Assistance*

We offer discount programs to patients under which the patient receives a discount on his or her prescription. We reimburse pharmacies for this discount through a third-party vendor. We record the total amount of estimated discounts for sales recorded in the period as a reduction of revenue, based on a combination of actual invoices received and an estimate of discounts to be paid for product in the sales channel, based on historical information.

#### *Sales Returns*

Consistent with industry practice, we maintain a return policy that allows customers to return product within a specified period prior to and subsequent to the product expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date and up to one year after its expiration date. The right of return expires on the earlier of one year after the product expiration date or the time that the product is dispensed to the patient. The majority of our product returns are the result of product dating, which falls within the range set by our policy, and are settled through the issuance of a credit to the customer. Our estimate of the provision for returns is based upon our historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which our customer may return product. This period is known to us based on the shelf lives of our products at the time of shipment. We record sales returns as an allowance against accounts receivable and a reduction of revenue.

#### *Prompt Pay Discounts*

As an incentive for prompt payment, we offer a 2% cash discount to customers. We expect that all customers will comply with the contractual terms to earn the discount. We record the discount as an allowance against accounts receivable and a reduction of revenue.

#### *Government Rebates and Chargebacks*

##### *Government Rebates*

We participate in certain federal government rebate programs, such as Medicare and Medicaid. We accrue estimated rebates based on estimated percentages of product sold to qualified patients, estimated rebate percentages and estimated levels of inventory in the distribution channel that will be sold to qualified patients, and we record the rebate as a reduction of revenue.

*Government Chargebacks*

We provide discounts to federal government qualified entities with whom we have contracted. These federal entities purchase products from the wholesale pharmaceutical distributors at a discounted price, and the wholesale pharmaceutical distributors then charge back to us the difference between the current retail price and the contracted price that the federal entities paid for the product. We accrue estimated chargebacks based on contract prices and sell-through sales data obtained from third party information, and we record the chargeback as a reduction of revenue.

**Table of Contents**

The following table summarizes our customer-related accruals and allowances as of September 30, 2014:

	<b>Contractual Allowances</b>	<b>Government Rebates and Chargebacks</b>	<b>Total</b>
Balance at December 31, 2013	\$ 6,716	\$ 1,407	\$ 8,123
Current provisions relating to sales in current year	151,906	22,730	174,636
Adjustments relating to prior year sales	(1,770)		(1,770)
Payments/returns relating to sales in current year	(97,197)	(21,142)	(118,339)
Payments/returns relating to sales in prior years	(4,842)	(1,307)	(6,149)
Vidara customer related accruals and allowances	472	13,528	14,000
<b>Balance at September 30, 2014</b>	<b>\$ 55,285</b>	<b>\$ 15,216</b>	<b>\$ 70,501</b>

*Cost of Goods Sold*

We recognize cost of goods sold in connection with our sales of DUEXIS, VIMOVO, ACTIMMUNE and RAYOS/LODOTRA.

Cost of goods sold for DUEXIS includes all costs directly related to the acquisition of product from our third-party manufacturers, including freight charges and costs of distribution.

Cost of goods sold for VIMOVO includes all costs directly related to the acquisition of product from AstraZeneca and/or a third-party manufacturer, amortization of intellectual property, royalty accretion expense and any changes in estimate associated with the contingent royalty liability as described in the accrued contingent royalty accounting policy below.

Cost of goods sold for ACTIMMUNE includes all costs directly related to the acquisition of ACTIMMUNE from our third-party manufacturer, Boehringer Ingelheim, including freight charges and other direct expenses such as insurance and amortization of intellectual property, royalty accretion expense and any changes in estimate associated with the contingent royalty liability as described in the accrued contingent royalty accounting policy below.

Cost of goods sold for RAYOS includes all costs directly related to the acquisition of product from our third-party manufacturers, including freight charges and costs of distribution, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

Cost of goods sold for LODOTRA includes raw material costs, costs associated with third parties who manufacture LODOTRA for us, supply chain costs, amortization of developed technology, royalty payments to third parties for the use of certain licensed patents and applicable taxes.

*Inventories*

Inventories are stated at the lower of cost or market value using the first-in, first-out method. Inventories consist of raw materials, work-in-process and finished goods. We have entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. Inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs. Inventories exclude product sample inventory, which are included in other current assets and are expensed as a component of sales and marketing expense when provided to physicians or healthcare providers.

*Intangible Assets*

Definite-lived intangible assets are amortized over their estimated useful lives. We review our intangible assets when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. We measure fair value based on the estimated future discounted cash flows associated with these assets in addition to other assumptions and projections that we deem to be reasonable and supportable. The estimated useful lives for all identified intangible assets that are subject to amortization were as follows as of September 30, 2014:

## Edgar Filing: Horizon Pharma plc - Form 10-Q

<b>Intangible asset</b>	<b>Estimated Useful Life (in years)</b>
LODOTRA and RAYOS developed technology	12
VIMOVO intellectual property	5
ACTIMMUNE developed technology	13
Customer relationships	10



---

**Table of Contents**

Indefinite-lived intangible assets consist of capitalized in-process research and development, or IPR&D. IPR&D assets represent capitalized incomplete research projects that we acquired through business combinations. Such assets are initially measured at their acquisition date fair values and are tested for impairment, until completion or abandonment of R&D efforts associated with the projects. An IPR&D asset is considered abandoned when R&D efforts associated with the asset have ceased, and there are no plans to sell or license the asset or derive value from the asset. At that point, the asset is considered to be disposed of and is written off. Upon successful completion of each project, we will make a determination about the then remaining useful life of the intangible asset and begin amortization. We test our indefinite-lived intangibles, including IPR&D assets, for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired.

*Fair Value of Financial Instruments*

The carrying amounts of our financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to their short maturities. At December 31, 2013 and at the final measurement on June 27, 2014, the estimated fair value of our derivative liability related to the convertible portion of our Convertible Senior Notes was derived utilizing the binomial lattice approach for the valuation of convertible instruments. Assumptions used in the calculation included, among others, determining the appropriate credit spread using benchmarking analysis and solving for the implied credit spread, calculating the fair value of the stock component using a discounted risk free rate and borrowing cost and calculating the fair value of the note component using a discounted credit adjusted discount rate. Based on the assumptions used to determine the fair value of the derivative liability associated with the Convertible Senior Notes, we concluded that these inputs were Level 3 inputs.

*Business Combinations*

We account for business combinations in accordance with the pronouncement guidance in ASC 805, *Business Combinations*, in which acquired assets and liabilities are measured at their respective estimated fair values as of the acquisition date. We may be required, as in the case of intangible assets or contingent royalties, to determine the fair value associated with these amounts by estimating the fair value using an income approach under the discounted cash flow method, which may include revenue projections and other assumptions made by us to determine the fair value.

*Provision for Income Taxes*

We account for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the year that the change is enacted. We also account for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return.

*Stock-Based Compensation*

We account for employee stock-based compensation by measuring and recognizing compensation expense for all stock-based payments based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. We estimate the fair value of our stock-based awards to employees using the Black-Scholes option pricing model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price, volatility, risk-free interest rate, the calculation of expected term and the fair value of the underlying ordinary shares on the date of grant, among other inputs.

We also account for stock options issued to non-employees based on the stock options' estimated fair value determined using the Black-Scholes option pricing model. The fair value of equity awards granted to non-employees are re-measured at each reporting date, and the resulting change in the fair value associated with such awards, if any, is recognized as a corresponding increase or reduction to stock-based compensation during the period.

*Accrued Contingent Royalties*

## Edgar Filing: Horizon Pharma plc - Form 10-Q

Our accrued contingent royalties consist of the contingent royalty obligations assumed by us related to our acquisitions of the U.S. rights to VIMOVO and Vidara (ACTIMMUNE). At the time of each acquisition, we assigned a fair value to the liability for royalties. The royalty liability was based on anticipated revenue streams utilizing the income approach under the discounted cash flow method. The estimated liability for royalties is increased over time to reflect the change in its present value, and accretion expense is recorded as part of cost of goods sold. We evaluate the adequacy of the estimated contingent royalty liability at least annually, or whenever events or changes in circumstances indicate that an evaluation of the estimate is necessary. As part of any evaluation, we adjust the carrying value of the liability to the present value of the revised estimated cash flows using the original discount rate.

**Table of Contents**

Any decrease or increase to the liability is recorded as an increase or reduction in cost of goods sold. The royalty liability is included in current and long-term accrued royalties on the consolidated balance sheets.

*New Accounting Pronouncements*

The Financial Accounting Standards Board issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard will be effective for us on January 1, 2017 and early adoption is not permitted. The new standard permits the use of either the retrospective or cumulative effect transition method on adoption. We are evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures, including which transition method we will adopt.

**LIQUIDITY, FINANCIAL POSITION AND CAPITAL RESOURCES**

We have incurred losses since our inception in June 2005 and, as of September 30, 2014, we had an accumulated deficit of \$689,072. We anticipate that we may continue to incur net losses until such time as the revenues we generate from DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA and, beginning in January 2015, PENNSAID 2%, or any additional products we may acquire or in-license are sufficient to cover our operating expenses. We expect that our sales and marketing expenses will continue to increase as a result of our commercialization of DUEXIS, VIMOVO, ACTIMMUNE and RAYOS/LODOTRA and, beginning in January 2015, PENNSAID 2%, including our planned expansion of our sales force. As a result, we will need to generate significant net product sales, and royalty and other revenues to achieve profitability.

We have financed our operations to date through equity financings, debt financings and the issuance of convertible notes. As of September 30, 2014, we had \$248,781 in cash and cash equivalents.

On March 18, 2014, HPI, Holdings, Vidara, U.S. HoldCo and Merger Sub entered into the Merger Agreement under which Merger Sub merged with and into HPI, with HPI continuing as the surviving corporation and as a wholly-owned, indirect subsidiary of Vidara, and with Vidara converting to a public limited company and changing its name to Horizon Pharma plc. Following the completion of the Merger, New Horizon is organized under the laws of Ireland. In the Merger, HPI's stockholders received one ordinary share of New Horizon in exchange for each share of HPI common stock they owned as of the closing. Upon the closing of the Merger, HPI's security holders (excluding the holders of the Convertible Senior Notes) owned approximately 74% of New Horizon and Holdings owned approximately 26% of New Horizon on a fully-diluted basis. At the closing, Holdings received a cash payment of \$210,871 and \$2,750 was paid into a temporary escrow account.

On June 17, 2014, HPI, as initial signatory, entered into a Credit Agreement with the lenders from time to time party thereto, or the Lenders, and Citibank, as administrative agent and collateral agent, and effective as of the closing of the Merger, U.S. HoldCo and the other borrowers from time to time party thereto, or the Borrowers, providing for (i) a five-year \$300,000 term loan facility, or the Senior Secured Credit Facility, the proceeds of which were used in part to effect the Merger and to pay fees and expenses in connection therewith and are being used in part for general corporate purposes, (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions, and (iii) one or more uncommitted refinancing loan facilities with respect to loans under the Credit Agreement. The Credit Agreement allows us and our subsidiaries to become borrowers under the accordion facility. On September 19, 2014, U.S. HoldCo borrowed the entire \$300,000 available under the Senior Secured Credit Facility. Loans under the Senior Secured Credit Facility bear interest, at each our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 8.00% per annum (subject to a 1.00% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 7.00% per annum.

Our obligations under the Credit Agreement and any swap obligations entered into with a Lender are guaranteed by us and each of our existing and subsequently acquired or organized direct and indirect subsidiaries, subject to limited exceptions. As of September 30, 2014 we have not entered into any swap obligations. Our obligations under the Credit Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected security interest in (i) all of our tangible and intangible assets, except for certain customary excluded assets, and (ii) all of the capital stock of our subsidiaries (limited, in the case of the stock of certain non-U.S. subsidiaries of U.S. HoldCo, to 65% of the capital stock of such subsidiaries).

We are permitted to make voluntary prepayments of loans under the Senior Secured Credit Facility, except that (i) a specified make-whole amount would apply to any repayment or repricing prior to September 19, 2016, (ii) a 4% premium would apply to any repayment or a repricing on or prior to September 19, 2017, and (iii) a 2% premium would apply to any repayment or a repricing on or prior to September 19, 2018. We are required to make mandatory prepayments of loans under the Senior Secured Credit Facility (without payment of a premium) with (a) net cash

## Edgar Filing: Horizon Pharma plc - Form 10-Q

proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (b) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions), and (c) net cash proceeds from issuances of debt (other than certain permitted debt).

---

**Table of Contents**

In connection with the signing the merger agreement with Vidara, HPI entered into a commitment letter, or the Commitment Letter, with Deerfield Management Company, L.P., or Deerfield, and certain funds managed by Deerfield, or the Deerfield Funds, pursuant to which the Deerfield Funds committed to provide up to \$250,000 of senior secured loans to finance the Merger. HPI allowed the Commitment Letter to expire on June 30, 2014 as a result of the execution of the Senior Secured Credit Facility.

On November 18, 2013, we entered into note purchase agreements with investors to issue \$150,000 aggregate principal amount of Convertible Senior Notes. The Convertible Senior Notes were issued on November 22, 2013. We received net proceeds of \$124,923 from the sale of the Convertible Senior Notes, after deducting fees and expenses of \$6,402 and \$18,675 related to a capped call transaction. The Convertible Senior Notes are governed by an Indenture, dated as of November 22, 2013, between HPI and U.S. Bank National Association, as trustee. In connection with the Merger, HPI and Horizon Pharma plc executed a supplemental Indenture dated as of September 19, 2014. Pursuant to the supplemental Indenture, HPI remains the obligor of the Convertible Senior Notes and Horizon Pharma plc agreed to fully and unconditionally guaranty the obligations of HPI under the Indenture. The supplemental Indenture also provides that the conversion value of the Convertible Senior Notes will be calculated by reference to the ordinary shares of Horizon Pharma plc, rather than the common stock of HPI, and any shares issuable upon conversion of the Convertible Senior Notes will be settled in ordinary shares of Horizon Pharma plc, rather than shares of the common stock of HPI. In addition, Horizon Pharma plc has assumed the disclosure obligations required by the Indenture.

The Convertible Senior Notes bear interest at a rate of 5.00% per year, payable in arrears on May 15 and November 15 of each year, beginning on May 15, 2014. The Convertible Senior Notes will mature on November 15, 2018, unless earlier repurchased or converted. The Convertible Senior Notes were sold at a price equal to 100% of the principal amount thereof and are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding August 15, 2018 only under certain conditions. On or after August 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date for the Convertible Senior Notes, holders will be able to convert their Convertible Senior Notes at their option at the conversion rate then in effect at any time, regardless of these conditions. Subject to certain limitations, HPI may settle conversions of the Convertible Senior Notes by paying or delivering, as the case may be, cash, our ordinary shares or a combination of cash and our ordinary shares, at HPI's election. If we undergo a fundamental change prior to the maturity date of the Convertible Senior Notes, the holders may require HPI to repurchase for cash all or any portion of their Convertible Senior Notes at a price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased, plus accrued and unpaid interest.

The conversion rate for the Convertible Senior Notes was initially 186.4280 ordinary shares per \$1,000 principal amount of Convertible Senior Notes (equivalent to an initial conversion price of approximately \$5.36 per ordinary share). The conversion rate of the Convertible Senior Notes, and the corresponding conversion price, is subject to adjustment for certain events, but will not be adjusted for accrued and unpaid interest.

On October 23, 2014 and October 27, 2014, we entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes. Under the conversion agreements, the holders agreed to convert an aggregate principal amount of \$69,434 of Convertible Senior Notes held by them and we agreed to settle such conversions by issuing 12,944,350 ordinary shares. In addition, pursuant to the conversion agreements, we made an aggregate cash payment of \$14,614 to the holders for additional exchange consideration and accrued and unpaid interest. The transactions closed on or before October 31, 2014. Immediately following the conversions of the Convertible Senior Notes contemplated by the conversion agreements, \$80,566 in aggregate principal amount of the Convertible Senior Notes remained outstanding.

During the nine months ended September 30, 2014, we received proceeds of \$33,256 in connection with our issuance of an aggregate of 7,300,853 of our ordinary shares upon the exercise of warrants. Additionally, we issued an aggregate of 599,769 ordinary shares in connection with the exercise of stock options and vesting of restricted stock units and received \$1,826 in proceeds in connection with the exercise of stock options, and received proceeds of \$649 upon the issuance of 264,110 ordinary shares through our employee stock purchase program.

We are required to maintain compliance with applicable Swiss laws with respect to our Swiss subsidiary, Horizon Pharma AG, including laws requiring maintenance of equity in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities. We review on a regular basis whether Horizon Pharma AG is overindebted. As of September 30, 2014, Horizon Pharma AG was not overindebted. However, Horizon Pharma AG has previously been overindebted, including at December 31, 2013. We will continue to monitor and review Horizon Pharma AG's financial position and, as necessary, will address any overindebtedness until such time as Horizon Pharma AG generates positive income at a statutory level, which could require us to have cash at Horizon Pharma AG in excess of its near term operating needs and could affect our ability to have sufficient cash to meet the near term operating needs of our other operating subsidiaries. As of September 30, 2014 and December 31, 2013, Horizon Pharma AG had cash and cash equivalents of \$3,651 and \$3,476, respectively. Based upon the cash and cash equivalents held by Horizon Pharma AG as of September 30, 2014 and December 31, 2013, we do not expect that our financial position or results of operations will be materially affected by any need to address overindebtedness at Horizon Pharma AG. To date, the overindebtedness of Horizon Pharma AG has not resulted in the need to divert material cash resources from our other operating subsidiaries.



**Table of Contents**

The following table provides a summary of our cash flows for the nine months ended September 30, 2014 and 2013:

	Nine Months Ended September 30,	
	2014	2013
Cash and cash equivalents	\$ 248,781	\$ 58,650
Cash provided by (used in):		
Operating activities	17,470	(43,109)
Investing activities	(181,057)	(643)
Financing activities	331,966	(1,745)

**Sources and Uses of Cash*****Operating Cash Flows***

During the nine months ended September 30, 2014, net cash provided by operating activities was \$17,470 compared to net cash used in operating activities of \$43,109 during the nine months ended September 30, 2013. The increase in net cash provided by operating activities was primarily attributable to higher cash collections from accounts receivable balances as a result of an increase in product sales, partially offset by higher cash outlays for trade payables, contractual allowances and government rebates and chargebacks. Cash provided by operating activities during 2014 was negatively impacted by \$29,043 of payments for transaction costs related to the Merger and \$14,116 of payments made for post-closing of certain of Vidara's transaction costs that we assumed.

***Investing Cash Flows***

During the nine months ended September 30, 2014 and 2013, net cash flows used in investing activities was \$181,057 and \$643, respectively. The increase in net cash used in investing activities during the nine months ended September 30, 2014 was primarily associated with the net cash paid for the acquisition of Vidara.

***Financing Cash Flows***

During the nine months ended September 30, 2014, net cash provided by financing activities was \$331,966 compared to net cash used in financing activities of \$1,745 during the nine months ended September 30, 2013. The increase in net cash provided by financing activities during the nine months ended September 30, 2014 was primarily attributable to \$300,000 of proceeds received from the borrowing from the Senior Secured Credit Facility in connection with the merger with Vidara on September 30, 2014, net of \$13,034 of original issue discount and deferred financing fees. In addition, during the nine months ended September 30, 2014, we received proceeds of \$33,256 in connection with the exercise of warrants to purchase 7,300,853 ordinary shares. We also received \$9,385 of cash proceeds from settlement of the capped call termination in September 2014.

**Contractual Obligations**

During the three months ended September 30, 2014, there were no material changes outside of the ordinary course of business to our contractual obligations as previously disclosed in Part II, Item 7 of HPI's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, except for the changes described below.

On June 17, 2014, we entered into the Senior Secured Credit Facility and on September 19, 2014, U.S. HoldCo borrowed the entire \$300,000 available under the Senior Secured Credit Facility. Loans under the Senior Secured Credit Facility bear interest, at each our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 8.00% per annum (subject to a 1.00% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 7.00% per annum.

On September 19, 2014, we and HPI executed a supplemental indenture related to the Convertible Senior Notes, pursuant to which HPI remains the obligor of the Convertible Senior Notes and we agreed to fully and unconditionally guaranty the obligations of HPI under the Indenture.

## Edgar Filing: Horizon Pharma plc - Form 10-Q

On October 23, 2014 and October 27, 2014, we entered into separate, privately-negotiated conversion agreements with certain holders of the Convertible Senior Notes. Under the conversion agreements, the holders agreed to convert an aggregate principal amount of \$69,434 of Convertible Senior Notes held by them and we agreed to settle such conversions by issuing 12,944,350 ordinary shares. In addition, pursuant to the conversion agreements, we made an aggregate cash payment of \$14,614 to the holders for additional exchange consideration and accrued and unpaid interest. The transactions closed on or before October 31, 2014. Immediately following the conversions of the Convertible Senior Notes contemplated by the conversion agreements, \$80,566 in aggregate principal amount of the Convertible Senior Notes remained outstanding.



**Table of Contents**

As a result of the Merger, in addition to the contractual obligations of HPI described in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, we became subject to the contractual obligations of Vidara, which were as follows as of September 30, 2014:

	Payments due by period				Total
	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years	
	(in thousands)				
Operating lease obligation(1)	\$ 13	\$ 163	\$ 48	\$	\$ 224
Purchase commitments(2)	3,900	11,700	7,800	3,900	27,300
<b>Total contractual cash obligations</b>	<b>\$ 3,913</b>	<b>\$ 11,863</b>	<b>\$ 7,848</b>	<b>\$ 3,900</b>	<b>\$ 27,524</b>

- (1) We are obligated under the terms of an operating lease arrangement for the office in Roswell, Georgia. The lease agreement for the office space in Roswell expires in October 2018.
- (2) Based on an estimate of the minimum order quantities required to be placed annually with Boehringer Ingelheim, using a Dollar-to-Euro rate of 1.38.

In addition to the obligations set out in the above table, we have assumed material obligations to pay royalties to certain third parties on net sales of ACTIMMUNE as result of the Merger.

Under the terms of the license agreement with Genentech Inc., which was the original developer of ACTIMMUNE, we are obligated to pay royalties to Genentech on its net sales of ACTIMMUNE as follows:

Through November 25, 2014, we are obligated to pay a royalty of 45% of the first \$3.7 million in net sales achieved in a calendar year, and 10% on all additional net sales in that year;

For the period from November 26, 2014 through May 5, 2018, the royalty payments will be reduced to a 20-30% range for the first tier in net sales and in the 1-9% range for the second tier; and

From May 6, 2018 and for so long as we continues to commercially sell ACTIMMUNE, we will be obligated to pay an annual royalty in the low single digits as a percentage of annual net sales.

Under the terms of its agreement with InterMune's parent company predecessor, Connetics Corporation (which is now part of GlaxoSmithKline), we are obligated to pay royalties to Connetics on our net sales of ACTIMMUNE as follows:

0.25% of net sales of ACTIMMUNE, rising to 0.5% once cumulative net sales of ACTIMMUNE in the United States surpass \$1.0 billion; and

In the event we develop and receive regulatory approval for ACTIMMUNE in the indication of scleroderma, we will be obligated to pay a royalty of 4% on all net sales of ACTIMMUNE recorded for use in that indication.

**Off-Balance Sheet Arrangements**

## Edgar Filing: Horizon Pharma plc - Form 10-Q

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities, other than the indemnification agreements discussed in Note 13, *Commitments and Contingencies* in the notes to our condensed consolidated financial statements included in this report.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to various market risks, which include potential losses arising from adverse changes in market rates and prices, such as interest rates and foreign exchange fluctuations. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

*Interest Rate Risk.* We are subject to interest rate fluctuation exposure through our investment in money market accounts which bear a variable interest rate. The goals of our investment policy are associated with the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market risk, we maintain our excess cash and cash equivalents in money market funds. Because of the short-term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

---

## **Table of Contents**

*Foreign Currency Risk.* Our purchase cost of ACTIMMUNE under our contract with Boehringer Ingelheim as well as our sales contracts relating to LODOTRA are principally denominated in Euros and are subject to significant foreign currency risk. We also incur certain operating expenses in currencies other than the U.S. dollar in relation to our Ireland operations and other foreign subsidiaries, including Horizon Pharma AG; therefore, we are subject to volatility in cash flows due to fluctuations in foreign currency exchange rates, particularly changes in the Euro. To date, we have not entered into any hedging contracts since exchange rate fluctuations have had minimal impact on our results of operations and cash flows.

*Inflation Risk.* We do not believe that inflation has had a material impact on our business or results of operations during the periods for which the condensed consolidated financial statements are presented in this report.

*Credit Risk.* Historically, our accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of large wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. For the nine months ended September 30, 2014, our top five customers, AmerisourceBergen, McKesson Corporation, Cardinal Health, Inc., Rochester Drug Company and American Specialty Pharmacy, Inc., accounted for approximately 90% of total consolidated gross sales. For the twelve months ended December 31, 2013, our top five customers, AmerisourceBergen, McKesson Corporation, Cardinal Health, Inc., Mundipharma and Rochester Drug Company, accounted for approximately 89% of total consolidated gross sales.

In addition, four customers, McKesson Corporation, AmerisourceBergen, American Specialty Pharmacy, Inc. and Cardinal Health, Inc., accounted for approximately 85% of our total outstanding accounts receivable balances at September 30, 2014. As of December 31, 2013, McKesson Corporation, AmerisourceBergen, Rochester Drug Company and Cardinal Health, Inc., accounted for approximately 85% of our total outstanding accounts receivable balances. Historically, we have not experienced any losses related to our accounts receivable balances.

## **Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.* As required by paragraph (b) of Rules 13a-15 and 15d-15 promulgated under the Exchange Act, our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2014, the end of the period covered by this report.

*Changes in Internal Control Over Financial Reporting.* As discussed above, on September 19, 2014, a wholly-owned subsidiary of Horizon Pharma plc (formerly known as Vidara Therapeutics International Public Limited Company) merged with and into HPI, with HPI surviving the merger and becoming a wholly-owned subsidiary of Horizon Pharma plc. HPI is treated as the acquiring company in the Merger for accounting purposes, and the Merger was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. As a result, the historical financial statements of Horizon Pharma plc reflect the financial position, results of operations and cash flows of HPI only. Following the Merger, the financial statements of the current period reflect the financial position, results of operations and cash flows of Horizon Pharma plc. The results of operations of the acquired Vidara business are included in the results of operations of Horizon Pharma plc beginning on September 19, 2014. Also, as a result of the Merger, the internal control over financial reporting utilized by HPI prior to the Merger became the internal control over financial reporting of our company, and we are currently in the process of evaluating and integrating Vidara's historical internal controls over financial reporting with ours.

During the quarter ended September 30, 2014, other than continuing changes to our internal control processes resulting from the Merger as discussed above, there have been no material changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents****PART II. OTHER INFORMATION****Item 1. Legal Proceedings**

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an Abbreviated New Drug Application, or ANDA, with the U.S. Food and Drug Administration, or FDA, for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., collectively Par, for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par's ANDA and/or prevent Par from selling a generic version of DUEXIS. In January 2013, we filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par's ANDA and/or prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, we entered into a settlement agreement, or Par settlement agreement, and license agreement, or Par license agreement, with Par relating to its patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both us and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par's generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par's generic version of DUEXIS prior to the generic entry date, collectively, the License. The License covers all patents owned or controlled by us during the term of the Par license agreement that would, absent the License, be infringed by the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the License become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.

Under the Par license agreement, we also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by us during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States.

We may terminate the Par license agreement if Par commits a material breach of the agreement that is not cured or curable within 30 days after we provide notice of the breach. We may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc. Florida, known as Actavis Laboratories FL, Inc., or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA's review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc., collectively WLF, seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. We, together with Jagotec have granted WLF a covenant not to sue with respect to US Patent Nos. 6,677,326 and 8,168,218, respectively, and accordingly these patents have been dismissed from the lawsuit. The Markman claim construction hearing took place on October 16, 2014. The Court has not yet set a trial date for the WLF action.

## Edgar Filing: Horizon Pharma plc - Form 10-Q

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.

## **Table of Contents**

Currently, patent litigation is pending in the District of New Jersey against four generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and have been consolidated for discovery purposes. They are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, Dr. Reddy's); (ii) Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, Lupin); (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, Mylan); and (iv) Watson Laboratories, Inc. Florida, known as Actavis Laboratories FL, Inc. and Actavis Pharma, Inc. (collectively, Actavis). Patent litigation in the District of New Jersey against a fifth generic company, Anchen Pharmaceuticals Inc., or Anchen, was dismissed after Anchen recertified under Paragraph III. We understand that Dr. Reddy's has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy's is now able to commercialize VIMOVO under AstraZeneca's Nexium patent rights. The settlement agreement, however, has no effect on the Pozen VIMOVO patents, which are still the subject of patent litigations. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy's notice letters were dated March 11, 2011 and November 20, 2012; the Lupin notice letters were dated June 10, 2011 and March 12, 2014; the Mylan notice letter was dated May 16, 2013; the Actavis notice letters were dated March 29, 2013 and November 5, 2013; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order and has set a pretrial schedule but has not yet set a trial date.

### **Item 1A: Risk Factors**

You should consider carefully the risks described below, together with all of the other information included in this report, and in our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in or continue to hold our ordinary shares. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our ordinary shares to decline, resulting in a loss of all or part of your investment.

The risk factors set forth below with an asterisk (\*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in Item 1A of our annual report on Form 10-K for the year ended December 31, 2013, as filed with the SEC by Horizon Pharma, Inc., to which we are the successor for reporting purposes under the Securities Exchange Act of 1934.

### **Risks Related to Our Business and Industry**

*Our ability to generate revenues from our products is subject to attaining significant market acceptance among physicians, patients and healthcare payers.\**

DUEXIS®, VIMOVO®, ACTIMMUNE® and RAYOS®/LODOTRA®, and other product or product candidates that we may develop, acquire, or in-license, such as PENNSAID 2% which we expect to begin commercializing in January 2015, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. In the U.S. market, we began selling DUEXIS in December 2011. We began commercial sales of RAYOS, which was approved by the U.S. Food and Drug Administration, or FDA, in July 2012, to a subset of rheumatologists in the fourth quarter of 2012 with the full launch to the majority of U.S. rheumatologists and key primary care physicians in late January 2013. Outside the United States, LODOTRA has been sold in a limited number of countries and sales may not grow to expected levels, in part because we depend on our distribution partner, Mundipharma International Corporation Limited, or Mundipharma, for commercialization outside the United States. With respect to DUEXIS, we have only received marketing approval in the United Kingdom, or UK, thus far, and even if it is approved in other European countries, we do not expect the opportunity in Europe to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded non-steroidal anti-inflammatory drugs, or NSAIDs, in Europe. There have been no sales of DUEXIS in the UK thus far. VIMOVO was launched in the U.S. market in the fourth quarter of 2010 by AstraZeneca AB, or AstraZeneca, under its license from Pozen Inc., or Pozen. Following our acquisition of the U.S. rights to VIMOVO in November 2013, we began selling VIMOVO in the first quarter of 2014. ACTIMMUNE was originally launched in the U.S. market in March 1991 by Genentech and in June 2012, Vidara Therapeutics International plc, or Vidara, acquired the intellectual property rights and certain assets related to the ACTIMMUNE product line. In September 2014, the businesses of Horizon Pharma, Inc. and Vidara were combined, and as a result we assumed the commercialization of ACTIMMUNE. In October 2014 we entered into an asset purchase agreement with Nuvo Research Inc. to acquire the U.S. rights to PENNSAID 2%, and we expect to begin commercializing PENNSAID 2% in the United States in January 2015. We believe that the degree of market acceptance and our ability to generate revenues from our products will depend on a number

of factors, including:

timing of market introduction of our products as well as competitive drugs;

**Table of Contents**

efficacy and safety of our products;

continued projected growth of the arthritis, pain and inflammation markets;

prevalence and severity of any side effects;

if and when we are able to obtain regulatory approvals for additional indications for our products;

acceptance by patients, primary care specialists and key specialists, including rheumatologists, orthopedic surgeons, pain specialists and specialists in pediatric immunology, allergy, infectious diseases and hematology/oncology;

availability of coverage and adequate reimbursement and pricing from government and other third-party payers;

the performance of our distribution partners, over which we have limited control;

potential or perceived advantages or disadvantages of our products over alternative treatments, including cost of treatment and relative convenience and ease of administration;

strength of sales, marketing and distribution support;

the price of our products, both in absolute terms and relative to alternative treatments;

impact of past and future product price increases;

our ability to maintain a continuous supply of product for commercial sale;

the effect of current and future healthcare laws; and

product labeling or product insert requirements of the FDA or other regulatory authorities.

With respect to DUEXIS and VIMOVO, studies indicate that physicians do not commonly co-prescribe gastrointestinal, or GI, protective agents to high-risk patients taking NSAIDs. We believe this is due in part to a lack of awareness among physicians prescribing NSAIDs of the risk of NSAID-induced upper GI ulcers, in addition to the inconvenience of prescribing two separate medications and patient compliance issues associated with multiple prescriptions. If physicians remain unaware of, or do not otherwise believe in, the benefits of combining GI protective agents with NSAIDs, our market opportunity for DUEXIS and VIMOVO will be limited. Some physicians may also be reluctant to prescribe DUEXIS or VIMOVO due to the inability to vary the dose of ibuprofen and naproxen, respectively, or if they believe treatment with NSAIDs or GI protective agents other than those contained in DUEXIS and VIMOVO, including those of our competitors, would be more effective for their patients. With respect to each of DUEXIS, VIMOVO and RAYOS/LODOTRA, their higher cost compared to the generic or branded forms of their active ingredients alone may limit adoption by physicians, patients and healthcare payers. With respect to ACTIMMUNE, while it is the only FDA-approved treatment for chronic granulomatous disease, or CGD, and severe, malignant osteopetrosis, or SMO, they are very rare conditions and, as a result, our ability to grow ACTIMMUNE sales will depend on our ability to further penetrate this limited market. If



## Edgar Filing: Horizon Pharma plc - Form 10-Q

DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA, PENNSAID 2% or any other product that we may seek approval for, acquire or in-license fail to attain market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

*Our current business plan is highly dependent upon our ability to successfully execute on our sales and marketing strategy for the commercialization of DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA and, beginning in January 2015, PENNSAID 2%. If we are unable to successfully execute on our sales and marketing strategy, we may not be able to generate significant product revenues or execute on our business plan.\**

Our strategy is to build a fully-integrated U.S.-focused biopharmaceutical company to successfully execute the commercialization of DUEXIS, VIMOVO, ACTIMMUNE, RAYOS and, beginning in January 2015, PENNSAID 2% in the U.S. market. We may not be able to successfully commercialize DUEXIS, VIMOVO, ACTIMMUNE, RAYOS or PENNSAID 2% in the United States. Prior to our commercial launch of DUEXIS in the United States in December 2011, we did not have any experience commercializing pharmaceutical products on our own. LODOTRA was commercially launched in Europe by our exclusive distribution partners Merck Serono and Mundipharma. In order to commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Although we have expanded our sales force to approximately 310 sales representatives in connection with our November 2013 acquisition of the U.S. rights to VIMOVO and our September 2014 acquisition of Vidara and we plan to further increase our sales force to approximately 385 sales representatives in connection with our recent acquisition of the U.S. rights to PENNSAID 2%, we currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market these products and any additional products we may acquire or in-license will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

**Table of Contents**

As a result of the evolving role of various constituents in the prescription decision making process, we adjusted the profile of the sales representatives we hire from those with traditional pharmaceutical sales experience to those with successful business to business experience. For example, we have faced challenges due to pharmacists increasingly switching a patient's intended prescription from DUEXIS and VIMOVO to a generic or over the counter brand of their active ingredients. We have faced similar challenges for RAYOS with respect to generic brands and could face similar challenges with respect to PENNSAID 2% due to the availability of generic versions of PENNSAID 1.5%. While we believe the new profile of our representatives is better suited for this evolving environment, we cannot be certain that our representatives will be able to successfully protect DUEXIS, VIMOVO, RAYOS and PENNSAID 2% prescriptions or that we will be able to continue attracting and retaining sales representatives with our desired profile and skills. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain commercial personnel. To the extent we rely on additional third parties to commercialize any approved products, we may receive less revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to successfully develop and maintain our own commercial organization or collaborate with a third-party sales and marketing organization, we would not be able to commercialize our product candidates and execute on our business plan.

Another key part of our commercial strategy is to drive prescriptions through our *Prescriptions-Made-Easy*, or PME, specialty pharmacy program. Through this program, physicians can have their patients' prescriptions for our products filled automatically, with the product shipped directly to the patient. Prescriptions that are filled through our PME program are therefore not subject to the efforts of traditional pharmacies to switch a physician's prescription of our products to a generic or over the counter brand. We expect that continued adoption of our PME program by physicians will be important to our ability to gain market share for our products as pressure from healthcare payors and pharmacy benefit managers, or PBMs, to use cheaper generic or over the counter brands instead of branded products increases. For example, two of the largest PBMs, which we estimate to currently control approximately 20% to 30% of prescriptions for DUEXIS and VIMOVO, are expected to place DUEXIS and VIMOVO on their exclusion lists beginning in 2015. Additional healthcare plans, including those that contract with these PBMs but use different formularies, may also choose to exclude our products from their formularies. To the extent we are unable to re-direct prescriptions currently filled through traditional pharmacies, including those associated with/controlled by these PBMs, to our PME program, we may experience a significant decline in DUEXIS and VIMOVO prescriptions as a result of formulary exclusions. Our ability to increase adoption of our PME program will depend on physician awareness and comfort with the program, and we have limited ability to influence whether physicians use our PME program to prescribe our products. If we are unable to increase adoption of our PME program for filling prescriptions of our products, our ability to maintain or increase prescriptions for our products will be impaired. In addition, we depend on a limited number of PME pharmacies to fulfill patient prescriptions under the PME program. The commercialization of our product and our operating results could be affected by any adverse events at any of those PME pharmacies.

If we are unable to successfully implement our commercial plans and drive adoption by patients and physicians of any approved products through our sales, marketing and commercialization efforts, or if our partners fail to successfully commercialize our products, then we will not be able to generate sustainable revenues from product sales which will have a material adverse effect on our business and prospects.

*Our future prospects are highly dependent on the success of DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA and, beginning in January 2015, PENNSAID 2%, and we may not be able to successfully commercialize these products. Failure to do so would adversely impact our financial condition and prospects.\**

**Table of Contents**

A substantial majority of our resources are focused on the commercialization of DUEXIS, VIMOVO, ACTIMMUNE and RAYOS in the United States and we expect to begin commercialization of PENNSAID 2% in the United States in January 2015. Our ability to generate significant product revenues and to achieve commercial success in the near term will initially depend almost entirely on our ability to successfully commercialize these products in the United States. DUEXIS has been approved for marketing in the UK but is not yet approved in any other countries in Europe and therefore, unless we obtain regulatory approval in other countries, DUEXIS may not be commercialized to any significant extent outside of the United States. Even if DUEXIS is approved in other European countries, we do not expect the opportunity in Europe to be material to our business given the current state of the market in Europe for pain products and the revenue being generated by existing branded NSAIDs in Europe. Following our acquisition of the U.S. rights to VIMOVO in November 2013, our strategy has included bringing VIMOVO's pricing in-line with DUEXIS and thereby significantly increasing the value realized per prescription. We cannot guarantee that this strategy will continue to be effective generally, due to negative reactions to price increases or otherwise. Our initial strategy for RAYOS is to solely focus on the rheumatology indications approved for RAYOS where our Phase 3 clinical trial data supports our commercial plans. We initially launched RAYOS in the United States to a subset of rheumatologists in the fourth quarter of 2012, and the full launch to the majority of U.S. rheumatologists and key primary care physicians occurred in late January 2013. Although LODOTRA is approved for marketing in more than 35 countries outside the United States, to date it has only been marketed in a limited number of countries. While we anticipate that LODOTRA will be marketed in additional countries as our distribution partner, Mundipharma, formulates its reimbursement strategy, the ability to market LODOTRA in additional countries will depend on Mundipharma's ability to obtain reimbursement approvals in these countries. Our strategy with respect to ACTIMMUNE includes pricing increases, pursuing label expansion for additional indications, such as Friedreich's ataxia, or FA, and possible expansions of our sales force, but we cannot be certain that our pricing strategy will not result in downward pressure on sales or that we will be able to successfully complete clinical trials and obtain regulatory approvals in additional indications. Even if we obtain additional marketing and reimbursement approvals, our product revenues in Europe are entirely dependent upon the marketing efforts of our exclusive distribution partner, over which we have no control. Before we can market and sell these products in a particular jurisdiction, we need to obtain necessary regulatory approvals (from the FDA in the United States and from similar foreign regulatory agencies in other jurisdictions) and in some jurisdictions, reimbursement authorization. There are no guarantees that we or our commercialization partners will obtain any additional regulatory approvals for our products. Even if we or our commercialization partners obtain additional regulatory approvals, we may never generate significant revenues from any commercial sales of our products. If we fail to successfully commercialize DUEXIS, VIMOVO, ACTIMMUNE, RAYOS or PENNSAID 2%, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be adversely affected.

*We are solely dependent on Mundipharma to commercialize LODOTRA in Europe and certain Asian, Latin American, Middle Eastern, African and other countries. Failure of Mundipharma or any other third parties to successfully commercialize our products and product candidates in the applicable jurisdictions could have a material adverse effect on our business.*

We rely on Mundipharma for commercialization of LODOTRA in various European countries and certain Asian, Latin American, Middle Eastern, African and other countries. We have limited contractual rights to force Mundipharma to invest significantly in commercialization of LODOTRA in its markets. In the event that Mundipharma or any other third party with any future commercialization rights to any of our products or product candidates fails to adequately commercialize those products or product candidates because it lacks adequate financial or other resources, decides to focus on other initiatives or otherwise, our ability to successfully commercialize our products or product candidates in the applicable jurisdictions would be limited, which would adversely affect our business, financial condition, results of operations and prospects. We have had disagreements with Mundipharma under our European agreements and may continue to have disagreements, which could harm commercialization of LODOTRA in Europe or result in the termination of our agreements with Mundipharma. We also rely on Mundipharma's ability to obtain regulatory approval for LODOTRA in certain Asian, Latin American, Middle Eastern, African and other countries. In addition, our agreements with Mundipharma may be terminated by either party in the event of a bankruptcy of the other party or upon an uncured material breach by the other party. If Mundipharma terminated its agreements with us, we may not be able to secure an alternative distributor in the applicable territory on a timely basis or at all, in which case our ability to generate revenues from the sale of LODOTRA would be materially harmed.

*Our products are subject to extensive regulation, and we may not obtain additional regulatory approvals for our products.*

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution and other possible activities relating to our product candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions.

To market any drugs outside of the United States, we and current or future collaborators must comply with numerous and varying regulatory and compliance related requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may

## Edgar Filing: Horizon Pharma plc - Form 10-Q

include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

---

**Table of Contents**

Applications for regulatory approval, including a marketing authorization application for marketing new drugs in Europe, must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. Regulatory authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

may not deem a product candidate to be adequately safe and effective;

may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;

may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;

may not approve the manufacturing processes or facilities associated with our product candidates;

may conclude that we have not sufficiently demonstrated long-term stability of the formulation for which we are seeking marketing approval;

may change approval policies (including with respect to our product candidates' class of drugs) or adopt new regulations; or

may not accept a submission due to, among other reasons, the content or formatting of the submission.

Even if we believe that data collected from our preclinical studies, CMC studies and clinical trials of our product candidates are promising and that our information and procedures regarding CMC are sufficient, our data may not be sufficient to support marketing approval by regulatory authorities, or regulatory interpretation of these data and procedures may be unfavorable. Even if approved, product candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed, restricted distribution methods or other limitations. Our business and reputation may be harmed by any failure or significant delay in obtaining regulatory approval for the sale of any of our product candidates. We cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

While we anticipate that LODOTRA will be marketed in additional countries as Mundipharma formulates its reimbursement strategy, the ability to market LODOTRA in additional countries will depend on Mundipharma's ability to obtain regulatory and reimbursement approvals in these countries. Similarly, our ability to market DUEXIS outside of the United States will depend on obtaining regulatory and reimbursement approval in any country where DUEXIS may be marketed. However, certain countries have a very difficult reimbursement environment and we may not obtain reimbursement approval in all countries where DUEXIS may be marketed, or we may obtain reimbursement approval at a level that would make marketing DUEXIS in certain countries not viable.

*Our limited history of commercial operations makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our ordinary shares.\**

Following our acquisition of Vidara in September 2014, we have four products approved in the United States, one product with broad approval for commercial sale in Europe, and another product approved only for commercial sale in the UK thus far. In addition we expect to begin commercializing PENNSAID 2% in the United States in January 2015 as a result of our recent acquisition of the U.S. rights to PENNSAID 2% from Nuvo. RAYOS/LODOTRA has been approved in the United States and over 30 other countries, including Australia, Korea, Israel and

## Edgar Filing: Horizon Pharma plc - Form 10-Q

select countries within Europe. However, we have a limited history of marketing LODOTRA through our distribution partners, and LODOTRA is not yet marketed in all of the countries where it has been approved. DUEXIS was approved in the United States on April 23, 2011, and in March 2013 we announced we were granted marketing authorization for DUEXIS in the UK, and we have generated limited revenues for DUEXIS to date. We began the commercial sale of RAYOS in the United States in the fourth quarter of 2012, the commercial sale of VIMOVO in the United States in the first quarter of 2014 and the commercial sale of ACTIMMUNE as a combined company with Vidara in September 2014. We expect to begin commercializing PENNSAID 2% in the United States in January 2015. We face considerable risks and difficulties as a company with limited commercial operating history, particularly as a global consolidated entity with operating subsidiaries that also have limited operating histories. If we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited commercial operating history, including our lack of any history commercializing PENNSAID 2%, and our limited history commercializing VIMOVO and, as a combined company, ACTIMMUNE, makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected. For example, we may underestimate the resources we will require to successfully integrate our commercial organization with Vidara's or to commercialize VIMOVO, ACTIMMUNE and PENNSAID 2% within our organization or not realize the benefits we expect to derive from our recent acquisitions.

*We only have U.S. rights to VIMOVO and PENNSAID 2% and have no control over the activities of AstraZeneca to commercialize VIMOVO outside of the United States or Nuvo or its licensees to commercialize PENNSAID 2% outside the United States, which could adversely impact commercialization of VIMOVO and PENNSAID 2% in the United States.*

**Table of Contents**

AstraZeneca has retained its existing rights to VIMOVO in territories outside of the United States, including the right to use the VIMOVO name and related trademark. Similarly, Nuvo has retained its rights to PENNSAID 2% in territories outside of the United States and has announced its intention to seek commercialization partners outside the United States. We have little or no control over AstraZeneca's activities with respect to VIMOVO outside of the United States or of Nuvo or its future commercial partners activities with respect to PENNSAID 2% outside of the United States, even though those activities could impact our ability to successfully commercialize VIMOVO and PENNSAID 2% in the United States. For example, AstraZeneca or its assignees or Nuvo or its assignees can make statements or use promotional materials with respect to VIMOVO or PENNSAID 2%, respectively, outside of the United States that are inconsistent with our positioning of the products in the United States, and could sell VIMOVO or PENNSAID 2%, respectively, in foreign countries, including Canada, at prices that are dramatically lower than the prices we expect to charge in the United States. These activities and decisions, while occurring outside of the United States, could harm our commercialization strategy in the United States, in particular because AstraZeneca is continuing to market the product outside the United States under the same VIMOVO brand name that we are using in the United States. In addition, product recalls or safety issues with VIMOVO or PENNSAID 2% outside the United States, even if not related to the commercial product we sell in the United States, could result in serious damage to the brand in the United States and impair our ability to successfully market VIMOVO and PENNSAID 2%. We also rely on AstraZeneca and will rely on Nuvo or its assignees to provide us with timely and accurate safety information regarding the use of VIMOVO or PENNSAID 2%, respectively, outside of the United States, as we have or will have limited access to this information ourselves.

*We rely on third parties to manufacture commercial supplies of all of our products, and we intend to rely on third parties to manufacture commercial supplies of any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.\**

The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities. We do not control the manufacturing processes of third-party manufacturers and are currently completely dependent on our third-party manufacturing partners sanofi-aventis U.S. LLC, or sanofi-aventis U.S., operating through Valeant Pharmaceuticals International, Inc., or Valeant, its manufacturing partner located in Laval, Canada for production of DUEXIS, and Jagotec AG, or Jagotec, a wholly-owned subsidiary of SkyePharma PLC, located in Lyon, France, for production of RAYOS/LODOTRA. In August 2011, SkyePharma leased their entire pharmaceutical manufacturing business to Aenova France SAS, or Aenova. As such, Aenova is now a subcontractor for Jagotec for the manufacture of RAYOS/LODOTRA, with our consent. Sanofi Winthrop Industrie in France has been qualified as a backup manufacturer for DUEXIS. Bayer Pharma AG in Germany has been qualified as a backup manufacturer for RAYOS/LODOTRA. In December 2011, Valeant acquired Dermik, a dermatology unit of sanofi-aventis U.S., which includes the Laval, Canada site. Although, Valeant has taken over management and operations at the Laval, Canada facility, our manufacturing agreement remains with sanofi-aventis U.S. We purchase the primary active ingredients for DUEXIS from BASF Corporation in Bishop, Texas and Dr. Reddy's in India, and the primary active ingredient for RAYOS/LODOTRA from Tianjin Tianyao Pharmaceuticals Co., Ltd. in China and Sanofi Chimie in France. With respect to VIMOVO, we rely on AstraZeneca, including through its existing third party manufacturing arrangements, to supply finished VIMOVO product through 2014. After 2014, AstraZeneca will no longer be obligated to supply VIMOVO to us and we will need to rely on our own third-party manufacturing arrangements to ensure continued supply. In connection with our acquisition of the U.S. rights to VIMOVO, we have entered into a long-term master manufacturing services and product agreement with Patheon Pharmaceuticals Inc., or Patheon, for the supply of finished VIMOVO product. We have entered into long-term supply agreements with Divis Laboratories Limited and Minakem Holding SAS for the supply of the active pharmaceutical ingredients, or APIs, of VIMOVO. In addition, we are required to obtain AstraZeneca's consent prior to engaging any third-party manufacturers for esomeprazole, one of the APIs in VIMOVO, other than the third-party manufacturer(s) currently used by AstraZeneca or its affiliates or licensees. To the extent such manufacturers are unwilling or unable to manufacture esomeprazole for us on commercially-acceptable terms, we cannot guarantee that AstraZeneca would consent to our use of alternate sources of supply.

With respect to ACTIMMUNE, we rely on an exclusive supply agreement with Boehringer Ingelheim RCV GmbH & Co KG, or Boehringer Ingelheim, for manufacturing and supply. However, Boehringer Ingelheim also manufactures interferon gamma 1-b to supply its own commercial needs in its licensed territory, and this may lead to capacity allocation issues and supply constraints to us. Furthermore, we do not have a substitute supplier for ACTIMMUNE and the process of identifying a substitute supplier and getting that supplier approved by the applicable regulatory authorities for manufacture and packaging of ACTIMMUNE can be a lengthy and costly process. ACTIMMUNE is manufactured by starting with cells from working cell bank samples which are derived from a master cell bank. We and Boehringer Ingelheim separately store multiple vials of the master cell bank. In the event of catastrophic loss at our or Boehringer Ingelheim's storage facility, it is possible that we could lose multiple cell banks and have the manufacturing capacity of ACTIMMUNE severely impacted by the need to substitute or replace the cell banks.

With respect to PENNSAID 2%, we rely on an exclusive supply agreement with Nuvo for manufacturing and supply. If Nuvo licenses its rights to PENNSAID 2% to commercialization partners outside of the United States, it is possible that Nuvo would also agree to manufacture and supply PENNSAID 2% for those partners. In that case, we would have no guarantee that fulfilling demand for PENNSAID 2% in territories outside the United States would impair Nuvo's ability to supply us with our requested quantities of PENNSAID 2% in the United States. In addition, while our supply agreement with Nuvo provides for the qualification of additional manufacturing sites for PENNSAID 2%, we and

## Edgar Filing: Horizon Pharma plc - Form 10-Q

Nuvo may not be successful in finding alternative manufacturers to supply PENNSAID 2% or agreeing to commercially reasonable terms with alternate suppliers.



---

**Table of Contents**

A key excipient used in PENNSAID as a penetration enhancer is dimethyl sulfoxide, or DMSO. Horizon and Nuvo rely on a sole proprietary form of DMSO for which we maintain a substantial safety stock. However, should something happen to this supply Horizon and Nuvo may not be able to qualify a second source.

If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to supply our primary active ingredients or manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products. To the extent any third-party manufacturers that we engage with respect to our products are different than those currently being used for commercial supply in the United States, the FDA will need to approve the facilities of those third-party manufacturers used in the manufacture of our products prior to our sale of any product using these facilities. If we cannot agree to terms with third-party manufacturers of VIMOVO APIs or the third party suppliers we engage do not have their facilities approved by the FDA with sufficient time to transition commercial supply of VIMOVO after 2014, we may experience supply shortages and our commercialization of VIMOVO would be substantially harmed.

Although we have entered into supply agreements for the manufacture of our products, our manufacturers may not perform as agreed or may terminate their agreements with us. Under our manufacturing and supply agreement with sanofi-aventis U.S., operating through Valeant, either we or sanofi-aventis U.S. may terminate the agreement upon an uncured breach by the other party or without cause upon two years prior written notice, so long as such notice is given after the third anniversary of the first commercial sale of DUEXIS. Under our master manufacturing services and product agreement with Patheon for finished VIMOVO product, either we or Patheon may terminate the agreement for uncured material breach by the other party or upon the other party's bankruptcy or insolvency, we may terminate the agreement if any regulatory authority takes any action or raises any objection that prevents us from commercializing the VIMOVO product and Patheon may terminate the agreement if we assign our rights or obligations under the agreement to a competitor of Patheon or to a party that, in the reasonable opinion of Patheon, is not a credit worthy substitute for us, or in certain other circumstances where we assign the agreement without Patheon's consent. Our manufacturing agreement with Boehringer Ingelheim has a term that runs until July 31, 2020, but the agreement may be terminated earlier by either us or Boehringer Ingelheim for an uncured material breach by the other party or upon the other party's bankruptcy or insolvency. Under our manufacturing and supply agreement with Jagotec, either we or Jagotec may terminate the agreement in the event of an insolvency, liquidation or bankruptcy of the other party or upon an uncured breach by the other party. While we have the right to receive a continuing supply of RAYOS/LODOTRA from Jagotec for a period of 24 months after termination, we would need to move our manufacturing to our alternate supplier of RAYOS/LODOTRA, Bayer Pharma AG, in such an event and we would have to qualify a new back-up manufacturer. The initial term of our supply agreement with Nuvo for PENNSAID 2% is through December 31, 2022, but the agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party.

In addition, we do not have the capability to package any of our products for distribution. Consequently, we have entered into an agreement with Temmler Werke GmbH, or Temmler, for packaging of RAYOS/LODOTRA in certain European countries and in the United States, as well as any additional countries as may be agreed to by the parties. We intend to sell drug product finished and packaged by either Temmler or an alternate packager. At the end of 2012, Temmler was acquired by the Aenova Group. Valeant manufactures and supplies DUEXIS to us in final, packaged form for the United States as well as any additional countries as may be agreed to by the parties. During 2014, AstraZeneca is obligated to supply us VIMOVO in final, packaged form under a transition agreement and will work with us to transfer product packaging to Patheon. After 2014, we expect that Patheon will supply final, packaged VIMOVO product pursuant to the master manufacturing services and product agreement we executed in connection with our acquisition of the U.S. rights to VIMOVO. Boehringer Ingelheim supplies final, packaged ACTIMMUNE to us and Nuvo is obligated to supply final, packaged PENNSAID 2% to us, in each case under exclusive supply agreements.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in the drug products or in the manufacturing facilities in which its products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that issues relating to the manufacture of any of our products will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize our products in the United States or provide any product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in our ability to meet commercial demand for our products will result in the loss of potential revenues and could

## Edgar Filing: Horizon Pharma plc - Form 10-Q

adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

---

**Table of Contents**

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

*We have experienced recent growth and have expanded the size of our organization substantially in connection with our acquisition of the U.S. rights to VIMOVO in November 2013 and our acquisition of Vidara in September 2014, and we may experience difficulties in managing this growth as well as expected additional growth in connection with our acquisition of the U.S. rights to PENNSAID 2%.\**

As of December 31, 2010, we employed 41 full-time employees as a consolidated entity. In anticipation of the commercial launch of DUEXIS, we hired 80 sales representatives during the period from September 2011 through October 2011. As of December 31, 2013 and September 30, 2014, we employed 304 and 463 full-time employees, respectively, as a consolidated entity. We plan to further increase the size of our sales force in connection with our recent acquisition of PENNSAID 2% to a total of approximately 385 representatives. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire in connection with the commercialization of our products, requiring us to hire and train new sales representatives. Our management, personnel, systems and facilities currently in place may not be adequate to support this recent and anticipated growth, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses.

As our commercialization plans and strategies develop, we will need to continue recruiting and training sales and marketing personnel and expect to need to expand the size of our employee base for managerial, operational, financial and other resources as a result of our recent acquisition of Vidara. Our ability to manage any future growth effectively may require us to do, among other things, the following:

continue to manage and expand the sales and marketing efforts for our existing products;

enhance our operational, financial and management controls, reporting systems and procedures;

expand our international resources;

successfully identify, recruit, hire, train, maintain, motivate and integrate additional employees;

establish and increase our access to commercial supplies of our products and product candidates;

expand our facilities and equipment; and

manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators, distributors and other third parties.

In particular, the merger of the businesses of Horizon Pharma, Inc. and Vidara Therapeutic International plc is subject to numerous uncertainties and risks and will require significant efforts and expenditures. For example, we are transitioning Horizon Pharma, Inc. from a standalone public Delaware corporation to being part of a combined company organized in Ireland. This combination has resulted in many changes, including significant changes in the corporate business and legal entity structure, the integration of Vidara and its personnel with those of Horizon, and changes in systems. We are currently undertaking numerous complex transition activities, and we may encounter unexpected difficulties or incur unexpected costs, including:

difficulties in achieving growth prospects from combining the business of Vidara with that of Horizon;

## Edgar Filing: Horizon Pharma plc - Form 10-Q

difficulties in the integration of operations and systems;

difficulties in the assimilation of employees and corporate cultures;

challenges in preparing financial statements and reporting timely results at both a statutory level for multiple entities and jurisdictions and at a consolidated level for public reporting;

challenges in keeping existing customers and obtaining new customers; and

challenges in attracting and retaining key personnel.

If any of these factors impair our ability to integrate the operations of Horizon with those of Vidara successfully or on a timely basis, we may not be able to realize the business opportunities, growth prospects and anticipated tax synergies from combining the businesses. In addition, we may be required to spend additional time or money on integration that otherwise would be spent on the development and expansion of our business.

---

## **Table of Contents**

Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities and towards managing these growth and integration activities. Our future financial performance and our ability to execute on our business plan will depend, in part, on our ability to effectively manage any future growth and our failure to effectively manage growth could have a material adverse effect on our business, results of operations, financial condition and prospects.

*If we are unable to effectively train and equip our sales force, our ability to successfully commercialize our products in the United States will be harmed.\**

As DUEXIS and RAYOS were not fully commercially launched in the United States until January 2012 and January 2013, respectively, and we did not begin commercializing VIMOVO in the United States until the first quarter of 2014, the members of our sales force have limited experience promoting the products. In addition, while the members of our sales force promoting ACTIMMUNE were previously promoting the product prior to the merger of the Horizon and Vidara businesses, we have not previously marketed ACTIMMUNE under Horizon's commercial organization. We expect to begin commercializing PENNSAID 2% in the United States in January 2015 and we currently have no experience marketing PENNSAID 2%. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense our products. In addition, we must train our sales force to ensure that a consistent and appropriate message about our products is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple products when they call on physicians and their office staff. This is particularly true with respect to DUEXIS, since VIMOVO is approved for similar indications and prescribed to similar patients, and prior to 2014 our sales representatives had previously been incentivized to increase DUEXIS market share at the expense of VIMOVO. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire, requiring us to train new sales representatives. As a result of the managed care environment and pharmacies switching patients' prescriptions to a generic or over the counter brand, we have had to adjust the profile of the sales representatives we hire from the traditional pharmaceutical representative to a representative with business to business experience that is focused on the total office call in order to protect the prescription the physician has written and ensure the patient receives what their doctor ordered, which includes driving adoption of our PME program. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of our products and their proper administration and label indication, as well as our PME program, our efforts to successfully commercialize our products could be put in jeopardy, which could have a material adverse effect on our financial condition, share price and operations.

*We face significant competition from other biotechnology and pharmaceutical companies, including those marketing generic products and our operating results will suffer if we fail to compete effectively.\**

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and international markets, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors and we will have to find new ways to compete and may have to potentially merge with or acquire other businesses to stay competitive. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or in-licensing on an exclusive basis, products that are more effective and/or less costly than our products.

DUEXIS and VIMOVO face competition from Celebrex<sup>®</sup>, marketed by Pfizer, and several other branded NSAIDs. DUEXIS and VIMOVO also face significant competition from the separate use of NSAIDs for pain relief and GI protective medications to reduce the risk of NSAID-induced upper GI ulcers. Both NSAIDs and GI protective medications are available in generic form and may be less expensive to use separately than DUEXIS or VIMOVO. PENNSAID 2% faces competition from generic versions of PENNSAID 1.5% and we expect that they will be priced significantly less than the price we intend to charge for PENNSAID 2% and Voltaren Gel, marketed by Endo Pharmaceuticals, which is the market leader in the topical NSAID category. Legislation enacted in most states in the United States allows or, in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Because pharmacists often have economic and other incentives to prescribe lower-cost generics, if physicians prescribe DUEXIS, VIMOVO or PENNSAID 2%, those prescriptions may not result in sales. If we are unsuccessful in convincing physicians to complete prescriptions through our PME program or otherwise provide prescribing instructions prohibiting the substitution of generic ibuprofen and famotidine separately as a substitution for DUEXIS or generic naproxen and branded Nexium (esomeprazole) as a substitute for VIMOVO or generic PENNSAID 1.5% as a substitute for PENNSAID 2%, sales of DUEXIS, VIMOVO and PENNSAID 2% may suffer despite any success we may have in promoting DUEXIS, VIMOVO or PENNSAID 2% to physicians. In addition, other product candidates that contain ibuprofen and famotidine in combination or naproxen and esomeprazole in combination, while not currently known to us, may be developed and compete with DUEXIS or VIMOVO, respectively, in the future.



---

**Table of Contents**

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an Abbreviated New Drug Application, or ANDA, with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. We subsequently filed patent infringement lawsuits against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., or collectively Par, relating to the ANDA and Par's intention to market a generic version of DUEXIS. On August 21, 2013, we entered into a settlement agreement, or the Par settlement agreement, and license agreement, or the Par license agreement, with Par relating to its patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both us and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances), or the License, to manufacture and commercialize Par's generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par's generic version of DUEXIS prior to the generic entry date. The License covers all patents owned or controlled by us during the term of the Par license agreement that would, absent the License, be infringed by the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the License become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.

Under the Par license agreement, we also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by us during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States.

The Par license agreement may be terminated by us if Par commits a material breach of the agreement that is not cured or curable within 30 days after we provide notice of the breach. We may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc. Florida, known as Actavis Laboratories FL, Inc., or Watson, advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA's review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Watson, Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc., or collectively WLF, seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. We, together with Jagotec have granted WLF a covenant not to sue with respect to US Patent Nos. 6,677,326 and 8,168,218, respectively, and accordingly these patents have been dismissed from the lawsuit. The Markman claim construction hearing took place on October 16, 2014. The Court has not yet set a trial date for the WLF action.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS containing up to 5 mg of prednisone. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.





**Table of Contents**

Currently, patent litigation is pending in the District of New Jersey against four generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and have been consolidated for discovery purposes. They are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd., or collectively, Dr. Reddy's; (ii) Lupin Ltd. and Lupin Pharmaceuticals Inc., or collectively, Lupin; (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc., or collectively, Mylan; and (iv) Watson Laboratories, Inc. Florida, known as Actavis Laboratories FL, Inc. and Actavis Pharma, Inc., or collectively, Actavis. Patent litigation in the District of New Jersey against a fifth generic company, Anchen Pharmaceuticals Inc., or Anchen, was dismissed after Anchen recertified under Paragraph III. We understand that Dr. Reddy's has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy's is now able to commercialize VIMOVO under AstraZeneca's Nexium patent rights. The settlement agreement, however, has no effect on the Pozen VIMOVO patents, which are still the subject of patent litigations. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy's notice letters were dated March 11, 2011 and November 20, 2012; the Lupin notice letters were dated June 10, 2011 and March 12, 2014; the Mylan notice letter was dated May 16, 2013; and the Actavis notice letters were dated March 29, 2013 and November 5, 2013; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order and has set a pretrial schedule but has not yet set a trial date.

If we are unsuccessful in any of the on-going patent litigations, we will likely face generic competition with respect to VIMOVO and/or RAYOS and our sales of VIMOVO and/or RAYOS will be substantially harmed.

ACTIMMUNE is the only drug currently approved by the FDA specifically for the treatment for CGD and SMO. While there are additional or alternative approaches used to treat patients with CGD and SMO, there are currently no products on the market that compete directly with ACTIMMUNE. The current clinical standard of care to treat CGD patients in the United States is the use of concomitant triple prophylactic therapy comprising ACTIMMUNE, an oral antibiotic agent and an oral antifungal agent. However, the FDA-approved labeling for ACTIMMUNE does not discuss this triple prophylactic therapy, and physicians may choose to prescribe one or both of the other modalities in the absence of ACTIMMUNE. Because of the immediate and life-threatening nature of SMO, the preferred treatment option for SMO is often to have the patient undergo a bone marrow transplant which, if successful, will likely obviate the need for further use of ACTIMMUNE in that patient. We are aware of a number of research programs investigating the potential of gene therapy as a possible cure for CGD. Additionally, other companies may be pursuing the development of products and treatments that target the same diseases and conditions which ACTIMMUNE is currently approved to treat. As a result, it is possible that our competitors may develop new drugs that manage CGD or SMO more effectively, cost less or possibly even cure CGD or SMO. In addition, U.S. healthcare legislation passed in March 2010 authorized the FDA to approve biological products, known as biosimilars, that are similar to or interchangeable with previously approved biological products, like ACTIMMUNE, based upon potentially abbreviated data packages. Biosimilars are likely to be sold at substantially lower prices than branded products because the biosimilar manufacturer would not have to recoup the research and development and marketing costs associated with the branded product. The development and commercialization of any competing drugs or the discovery of any new alternative treatment for CGD or SMO could have a material adverse effect on sales of ACTIMMUNE and its profitability.

The availability and price of our competitors' products could limit the demand, and the price we are able to charge, for our products. We will not successfully execute on our business objectives if the market acceptance of our products is inhibited by price competition, if physicians are reluctant to switch from existing products to our products, or if physicians switch to other new products or choose to reserve our products for use in limited patient populations.

In addition, established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license and develop novel compounds that could make our products obsolete. Our ability to compete successfully with these companies and other potential competitors will depend largely on our ability to leverage our experience in clinical, regulatory and commercial development to:

develop, acquire or in-license medicines that are superior to other products in the market;

attract qualified clinical, regulatory, and sales and marketing personnel;

obtain patent and/or other proprietary protection for our products and technologies;

obtain required regulatory approvals; and

successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new product candidates.

## **Table of Contents**

In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to be approved and overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, obtaining FDA approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business. The inability to compete with existing products or subsequently introduced products would have a material adverse impact on our business, financial condition and prospects.

*A variety of risks associated with operating our business and marketing our products internationally could materially adversely affect our business.\**

In addition to our U.S. operations, we have operations in Ireland, Switzerland and Germany. Moreover, LODOTRA is currently being marketed in a limited number of countries outside the United States, and Mundipharma is in the process of obtaining pricing and reimbursement approval for, and preparing to market, LODOTRA in other European countries, as well as in certain Asian, Latin American, Middle Eastern and African countries. Also, Grünenthal S.A. is in the registration process for the commercialization of DUEXIS in Latin America. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

compliance with differing or unexpected regulatory requirements for our products;

compliance with Irish laws and the maintenance of our Irish tax residency with respect to our overall corporate structure and administrative operations, including the need to generally hold meetings of our board of directors and make decisions in Ireland, which may make certain corporate actions more cumbersome, costly and time-consuming;

compliance with Swiss laws with respect to our Horizon Pharma AG subsidiary, including laws requiring maintenance of cash in the subsidiary to avoid overindebtedness, which requires Horizon Pharma AG to maintain assets in excess of its liabilities;

difficulties in staffing and managing foreign operations;

in certain circumstances, including with respect to the commercialization of LODOTRA in Europe and certain Asian, Latin American, Middle Eastern and African countries, and commercialization of DUEXIS in Latin America, increased dependence on the commercialization efforts and regulatory compliance of our distributors or strategic partners;

compliance with German laws with respect to our Horizon Pharma GmbH subsidiary through which Horizon Pharma AG conducts most of its European operations;

foreign government taxes, regulations and permit requirements;

United States and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;

anti-corruption laws, including the Foreign Corrupt Practices Act;

economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;

fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;

compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;

workforce uncertainty in countries where labor unrest is more common than in the United States;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;

changes in diplomatic and trade relationships; and

challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

*If we fail to develop, acquire or in-license other product candidates or products, our business and prospects would be limited.\**

---

**Table of Contents**

A key element of our strategy is to develop, acquire or in-license and commercialize a portfolio of other product candidates in addition to DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA and PENNSAID 2%. Because we do not have proprietary drug discovery technology, the success of this strategy depends in large part upon the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically enabled product candidates for the treatment of pain-related diseases, or for therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring, licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited.

Moreover, any product candidate we identify, select and acquire or license may require additional, time-consuming development or regulatory efforts prior to commercial sale, including preclinical studies if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that is inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop our products, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates to follow our existing products, and our business and prospects would therefore be harmed.

*Our November 2013 acquisition of the U.S. rights to VIMOVO, the September 2014 merger with Vidara and our October 2014 acquisition of the U.S. rights to PENNSAID 2%, and any other strategic transactions that we may pursue in the future could have a variety of negative consequences, and we may not realize the benefits of such transactions or attempts to engage in such transactions.\**

We acquired the U.S. rights to VIMOVO in November 2013, merged the businesses of Horizon Pharma, Inc. and Vidara in September 2014 and acquired the U.S. rights to PENNSAID 2% in October 2014, and from time to time, we may seek to engage in additional strategic transactions with third parties, such acquisitions of companies or divisions of companies, asset purchases or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. We may also consider a variety of other business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and other investments. Any such transaction may require us to incur non-recurring and other charges, increase our near and long-term expenditures, pose significant integration challenges, create additional tax, legal, accounting and operational complexities in our business, require additional expertise, result in dilution to our existing shareholders and disrupt our management and business, which could harm our operations and financial results. For example, in connection with our acquisition of the U.S. rights to VIMOVO, we assumed primary responsibility for the existing patent infringement litigation with respect to VIMOVO, and have also agreed to reimburse certain legal expenses of Pozen with respect to its continued involvement in such litigation, and we expect that this will result in substantial on-going expenses and potential distractions to our management team. Because VIMOVO is approved for similar indications and prescribed to similar patients compared to DUEXIS, we may also experience lower prescriptions of DUEXIS as we seek to commercialize VIMOVO, particularly from the approximately 30% of physicians that currently prescribe both products. Moreover, we face significant competition in seeking appropriate strategic partners and transactions, and the negotiation process for any strategic transaction can be time-consuming and complex. In addition, we may not be successful in our efforts to engage in certain strategic transactions because our financial resources and research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential. We may not be able to expand our business or realize our strategic goals if we do not have sufficient funding or cannot borrow or raise additional capital. There is no assurance that following our acquisition of the U.S. rights to VIMOVO, the merger with Vidara, our acquisition of the U.S. rights to PENNSAID 2% or any other strategic transaction, we will achieve the anticipated revenues, net income or tax benefits that we believe to justify such transaction. Any failures or delays in entering into strategic transactions could also delay or negatively impact the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. In addition, any failures or delays in entering into strategic transactions anticipated by analysts or the investment community could result in a decline in our share price.

*We may not be able to successfully maintain our low tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.\**



## Table of Contents

We are incorporated in Ireland and maintain subsidiaries in multiple jurisdictions, including the United States, Switzerland, Luxemburg and Bermuda. Vidara was able to achieve a low average tax rate through the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions, including Ireland and Bermuda, together with intra-group service and transfer pricing agreements, each on an arm's length basis. We are continuing a substantially similar structure and arrangements. Taxing authorities, such as the U.S. Internal Revenue Service, or IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. We expect that these challenges will continue as a result of the recent increase in scrutiny and political attention on corporate tax structures. The IRS may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

*The IRS may not agree with our conclusion that we should be treated as a foreign corporation for U.S. federal income tax purposes following the combination of the businesses of Horizon Pharma, Inc. and Vidara Therapeutics International plc.\**

Although Horizon Pharma plc is incorporated in Ireland, the IRS, may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended, or the Code. A corporation is generally considered a tax resident in the jurisdiction of its organization or incorporation for U.S. federal income tax purposes. Because Horizon Pharma plc, the parent company of our organization, is an Irish incorporated entity, it would generally be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 provides an exception pursuant to which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal income tax purposes.

Under Section 7874, and as a result of the fact that the former shareholders of Horizon owned (within the meaning of Section 7874) less than 80% (by both vote and value) of the combined entity's stock immediately after the merger we believe we qualify as a foreign corporation for U.S. federal income tax purposes following the merger. However, there can be no assurance that there will not exist in the future a subsequent change in the facts or in law which might cause us to be treated as a domestic corporation for U.S. federal income tax purposes, including with retroactive effect.

Further, there can be no assurance that the IRS will agree with the position that the ownership test was satisfied. There is limited guidance regarding the application of Section 7874 of the Code, including with respect to the provisions regarding the application of the ownership test. If we were unable to be treated as a foreign corporation for U.S. federal income tax purposes, one of our significant strategic reasons for completing the Vidara merger would be nullified and we may not be able to recoup the significant investment in completing the transaction.

*Future changes to U.S. and non-U.S. tax laws could materially adversely affect us.\**

Under current law, we expect to be treated as a foreign corporation for U.S. federal income tax purposes following the Vidara merger. However, changes to the rules in Section 7874 of the Code or regulations promulgated thereunder or other guidance issued by the Treasury or the IRS could adversely affect our status as a foreign corporation for U.S. federal income tax purposes, and any such changes could have prospective or retroactive application to us or our shareholders. On May 20, 2014 Senator Carl Levin and Representative Sander M. Levin introduced The Stop Corporate Inversions Act of 2014 (the "bill") in the Senate and House of Representatives, respectively. In its current form, the bill would treat us as a U.S. Corporation as a result of the former shareholders of Horizon Pharma, Inc. owning 50% or more of the combined entity's stock immediately following the Vidara merger. If enacted, the bill would apply to taxable years ending after May 8, 2014 and does not contain an exception for transactions subject to a binding commitment on that date.

In addition, the U.S. Congress, the Organization for Economic Co-operation and Development, and other Government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations and there are several current legislative proposals that, if enacted, would substantially change the U.S. federal income tax system as it relates to the taxation of multinational corporations. One example is in the area of base erosion and profit shifting, where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the United States and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could materially and adversely affect us.

*If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.\**





---

## Table of Contents

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, sales and marketing and scientific and medical personnel, including our Chairman, President and Chief Executive Officer, Timothy P. Walbert; our Executive Vice President and Chief Business Officer, Robert F. Carey; our Executive Vice President and Chief Financial Officer, Paul W. Hoelscher; our Executive Vice President, Development, Manufacturing and Regulatory Affairs and Chief Medical Officer, Jeffrey W. Sherman, M.D., and other members of our executive committee. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide incentive stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, sales and marketing, regulatory affairs, clinical affairs, medical affairs and development teams may terminate their employment with us on short notice. Although we have written employment arrangements with all of our employees, these employment arrangements generally provide for at-will employment, which means that our employees can leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. We do not maintain key man insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior sales and marketing and scientific and medical personnel.

Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products and product candidates will be limited.

*We are, with respect to DUEXIS, VIMOVO, ACTIMMUNE and RAYOS, and will be, with respect to PENNSAID 2% and any other product candidate for which we obtain FDA approval or acquire or in-license, subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense. Additionally, any other product candidate, if approved by the FDA, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.\**

Any regulatory approvals that we obtain for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMPs, good clinical practices, or GCPs, international conference on harmonization regulations, or ICH regulations, and good laboratory practices, or GLPs, which are regulations and guidelines enforced by the FDA for all of our products in clinical development, for any clinical trials that we conduct post-approval. In connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we assumed responsibility for completing an ongoing Pediatric Research Equity Act post-marketing requirement study in children 12 years to 16 years and 11 months of age with Juvenile RA for which the FDA recently granted an extension with a final report due date of December 2015. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

fines, Warning Letters or holds on clinical trials;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;

## Edgar Filing: Horizon Pharma plc - Form 10-Q

product seizure or detention, or refusal to permit the import or export of products; and

injunctions, the imposition of civil or criminal penalties, or exclusions.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

*Coverage and reimbursement may not be available, or reimbursement may be available at only limited levels, for our products, which could make it difficult for us to sell our products profitably or to successfully execute planned product price increases.\**

---

**Table of Contents**

Market acceptance and sales of our products will depend in large part on global coverage and reimbursement policies and may be affected by future healthcare reform measures, both in the United States and other key international markets. Successful commercialization of our products will depend in part on the availability of governmental and third-party payer reimbursement for the cost of our products. Government health administration authorities, private health insurers and other organizations generally provide reimbursement for healthcare. In particular, in the United States, private health insurers and other third-party payers often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. These pressures may create negative reactions to any product price increases, or limit the amount by which we may be able to increase our product prices, which may adversely affect our product sales and results of operations. Even though we have contracts with PBMs, that does not guarantee that they will perform in accordance with the contracts, nor does it preclude them from taking adverse actions against us, which could materially adversely affect our operating results. For example, we were recently informed that two significant PBMs would be placing DUEXIS and VIMOVO on their exclusion lists beginning in 2015, which will result in a loss of reimbursement for patients whose healthcare plans have adopted these PBM lists. Additional healthcare plan formularies may also exclude our products from reimbursement due to the actions of these PBMs, future price increases we may implement, our use of co-pay programs, or other reasons. If our strategies to mitigate formulary exclusions are not effective, these events may reduce the likelihood that physicians prescribe our products and increase the likelihood that prescriptions for our products are not filled.

Outside of the United States, the success of our products, including LODOTRA and, if widely approved, DUEXIS, will depend largely on obtaining and maintaining government coverage, because in many countries patients are unlikely to use prescription drugs that are not covered by their government healthcare programs. To date, LODOTRA is approved in over 35 countries outside the United States, and reimbursement for LODOTRA has been obtained in Germany, Italy, Sweden and Switzerland. Mundipharma is seeking coverage for LODOTRA in a number of countries and currently sells LODOTRA without coverage in a limited number of countries. Negotiating coverage and reimbursement with governmental authorities can delay commercialization by 12 months or more. Coverage and reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and we expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, which we believe has impacted the reimbursement rates and timing to launch for LODOTRA to date, and we expect these discounts to continue as countries attempt to manage healthcare expenditures, especially in light of current economic conditions. For example, legislation was recently enacted in Germany that will increase the rebate on prescription pharmaceuticals and likely lower the revenues from the sale of LODOTRA in Germany that we would otherwise receive. As a result of these pricing practices, it may become difficult to achieve profitability or expected rates of growth in revenue or results of operations. Any shortfalls in revenue could adversely affect our business, financial condition and results of operations.

In light of such policies and the uncertainty surrounding proposed regulations and changes in the coverage and reimbursement policies of governments and third-party payers, we cannot be sure that coverage and reimbursement will be available for DUEXIS or LODOTRA in any additional markets or for any other product candidates that we may develop. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If coverage and reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products.

We expect to experience pricing pressures in connection with the sale of our products, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. There may be additional pressure by payers and healthcare providers to use generic drugs that contain the active ingredients found in DUEXIS, VIMOVO, RAYOS/LODOTRA and PENNSAID 2% or any other product candidates that we may develop, acquire or in-license. If we fail to successfully secure and maintain coverage and adequate reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, results of operations, financial condition and prospects. We may also experience pressure from payers concerning certain promotional approaches that we may implement such as co-pay programs whereby we assist patients to achieve an acceptable co-pay for our product, which may be contrary to payers' financial interests. If we are unsuccessful with our co-pay initiatives, we would be at a competitive disadvantage in terms of pricing versus preferred branded and generic competitors.



---

## **Table of Contents**

*We are subject to federal, state and foreign healthcare laws and regulations and implementation or changes to such healthcare laws and regulations could adversely affect our business and results of operations.\**

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to regulate and to change the healthcare system in ways that could affect our ability to sell our products profitably. In the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to civil and/or criminal penalties, damages, fines, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business.

We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. An expansion in the government's role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product utilization and adversely affect our business and results of operations. It is unclear whether and to what extent, if at all, other anticipated developments resulting from the federal healthcare reform legislation, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset the annual excise tax (on certain drug product sales) enacted under the PPACA, subject to limited exceptions. It is possible that the tax burden, if we are not excepted, would adversely affect our financial performance, which in turn could cause the price of our share to decline. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current products and/or those for which we may receive regulatory approval in the future.

*We are subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.*

In the United States, we are subject directly, or indirectly through our customers, to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, federal and state privacy and security laws, sunshine laws, government price reporting laws, and other fraud laws, as described in greater detail in the Government Regulation Section of this report. These laws may impact, among other things, our proposed sales, marketing and educational programs, as well as other possible relationships with customers, payers, and patients.

Compliance with these laws, including the development of a comprehensive compliance program, is difficult, costly and time consuming and companies that do not comply with these state laws face civil penalties. Even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend our business activities against enforcement or litigation, in light of the fact that there is significant enforcement interest in pharmaceutical companies in the United States, and some of the applicable laws are quite broad in scope with very narrow exceptions.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

*Our products or any other product candidate that we develop may cause undesirable side effects or have other properties that could delay or prevent regulatory approval or commercialization, result in product re-labeling or withdrawal from the market or have a significant impact on customer demand.\**

Undesirable side effects caused by any product candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, or cause us to evaluate the future of our development programs. In our two Phase 3

## Edgar Filing: Horizon Pharma plc - Form 10-Q

clinical trials with DUEXIS, the most commonly reported treatment-emergent adverse events were nausea, dyspepsia, diarrhea, constipation and upper respiratory tract infection. In Phase 3 endoscopic registration clinical trials with VIMOVO, the most commonly reported treatment-emergent adverse events were erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, nausea and upper respiratory tract infection. The most common side effects observed in pivotal trials for ACTIMMUNE were flu-like or constitutional symptoms such as fever, headache, chills, myalgia and fatigue. The most commonly reported treatment-emergent adverse events in the Phase 3 clinical trials with RAYOS/LODOTRA included flare in RA-related symptoms, abdominal pain, nasopharyngitis, headache, flushing, upper respiratory tract infection, back pain and weight gain. The most common adverse events reported in a Phase 2 clinical trial of PENNSAID 2% were application site reactions, such as dryness, exfoliation, erythema, pruritus, pain, induration, rash and scabbing.

---

## **Table of Contents**

In addition, the FDA or other regulatory authorities may require, or we may undertake, additional clinical trials to support the safety profile of our product candidates.

In addition, if we or others identify undesirable side effects caused by our products or any other product candidate that we may develop that receives marketing approval, or if there is a perception that the product is associated with undesirable side effects:

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;

regulatory authorities may withdraw their approval of the product or place restrictions on the way it is prescribed; and

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product or implement a risk evaluation and mitigation strategy.

If any of these events occurred with respect to our products, our ability to generate significant revenues from the sale of these products would be significantly harmed.

*We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or if they experience regulatory compliance issues, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.\**

We have agreements with third-party contract research organizations, or CROs, to conduct our clinical programs, including those required for post-marketing commitments. We may also have the need to enter into other such agreements in the future if we were to develop other product candidates or conduct clinical trials in additional indications for our existing products. We rely heavily on these parties for the execution of our clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol. We and our CROs are required to comply with current GCP or ICH regulations. The FDA enforces these GCP or ICH regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP or ICH regulations, the data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCP or ICH regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our products and product candidates. As a result, our results of operations and the commercial prospects for our products and product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition or prospects.

In addition, pursuant to a March 2011 letter agreement and in connection with our waiver of certain milestone payments, Mundipharma initiated a separate Phase 3 clinical trial for LODOTRA for the potential treatment of polymyalgia rheumatica, or PMR. We had limited control over the timing and implementation of the planned clinical trial and in February 2014, Mundipharma informed us that they had terminated the clinical trial primarily due to recruitment difficulties based on the inclusion criteria and as a result of the cessation of production of the comparator product Decortin® 1mg.





## Table of Contents

We also, as part of the April 23, 2011 FDA approval of DUEXIS, had a commitment under the Pediatric Research Equity Act, or PREA, to conduct an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients. We were notified by FDA on October 2, 2014 that we had either met or they had released us from all of the requirements under such assessment and we are in the process of winding down the remaining open study.

In addition, in connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we assumed responsibility for completing an ongoing PREA post-marketing requirement study in children 12 years to 16 years and 11 months of age with Juvenile Idiopathic Arthritis for which the FDA recently granted an extension with a final report due date of December 2015. Although we are committed to carrying out these commitments, there are challenges in conducting studies in pediatric patients including availability of study sites, patients, and obtaining parental informed consent.

*Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.\**

Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of potential product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical testing.

To the extent that we are required to conduct additional clinical development of DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA or PENNSAID 2% or we conduct clinical development of earlier stage product candidates or for additional indications for ACTIMMUNE or RAYOS/LODOTRA, we may experience delays in these clinical trials. We do not know whether any additional clinical trials will be initiated in the future, begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

obtaining regulatory approval to commence a trial;

reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

obtaining institutional review board or ethics committee approval at each site;

recruiting suitable patients to participate in a trial;

having patients complete a trial or return for post-treatment follow-up;

clinical sites dropping out of a trial;

adding new sites; or

manufacturing sufficient quantities of product candidates for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we expect to rely on CROs and

## Edgar Filing: Horizon Pharma plc - Form 10-Q

clinical trial sites to ensure the proper and timely conduct of our future clinical trials and while we intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or if we terminate, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

---

**Table of Contents**

*Business interruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.\**

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. While we carry insurance for certain of these events and have implemented disaster management plans and contingencies, the occurrence of any of these business interruptions could seriously harm our business and financial condition and increase our costs and expenses. Following the closing of our acquisition of Vidara, we conduct or plan to conduct significant management operations at both our global headquarters located in Dublin, Ireland and our U.S. headquarters located in Deerfield, Illinois. If our Dublin or Deerfield offices were affected by a natural or man-made disaster or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. We currently rely, and intend to rely in the future, on third-party manufacturers and suppliers to produce our products. Our ability to obtain commercial supplies of our products could be disrupted and our results of operations and financial condition could be materially and adversely affected if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The ultimate impact of such events on us, our significant suppliers and our general infrastructure is unknown.

*If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.\**

We face an inherent risk of product liability as a result of the commercial sales of our products and the clinical testing of our product candidates. For example, we may be sued if any of our products or product candidates allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for our products or product candidates that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management's time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

exhaustion of any available insurance and our capital resources;

the inability to commercialize our products or product candidates; and

a decline in our share price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies and commercial product sales in the amount of \$20 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the on-going commercialization of DUEXIS, VIMOVO, ACTIMMUNE and RAYOS in the United States, the planned commercialization of PENNSAID 2% in the United States, and/or the potential commercial launches of DUEXIS and LODOTRA in additional markets, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

*Our business involves the use of hazardous materials, and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.*

**Table of Contents**

Our third-party manufacturers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers are subject to federal, state and local as well as foreign laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state, federal or foreign authorities may curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage. If we are subject to any liability as a result of our third-party manufacturers' activities involving hazardous materials, our business and financial condition may be adversely affected. In the future we may seek to establish longer term third-party manufacturing arrangements, pursuant to which we would seek to obtain contractual indemnification protection from such third-party manufacturers potentially limiting this liability exposure.

*Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.*

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

**Risks Related to Our Financial Position and Capital Requirements**

*We have incurred significant operating losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.\**

We have a limited operating history and even less history operating as a combined organization following the Vidara merger. We have financed our operations primarily through equity and debt financings and the issuance of convertible notes and have incurred significant operating losses since our inception. We had net losses of \$232.0 million for the nine months ended September 30, 2014 and \$149.0 million, \$87.8 million and \$113.3 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of September 30, 2014, we had an accumulated deficit of \$692.9 million. We do not know whether or when we will become profitable. Our prior losses, combined with possible future losses, have had and will continue to have an adverse effect on our shareholders' deficit and working capital. Our losses have resulted principally from costs incurred in our development activities for our products and product candidates, commercialization activities related to our product launches and costs associated with derivative liability accounting. We anticipate that we will continue to incur operating losses until such time as the revenues we generate from the sale of our products are sufficient to cover our operating expenses.

*We have limited product revenues and other sources of revenues. We may never achieve or sustain profitability, which would depress the market price of our ordinary shares and could cause our investors to lose all or a part of their investment.\**

Our ability to become profitable depends upon our ability to generate revenues from sales of our products. DUEXIS was approved by the FDA on April 23, 2011, and we began generating revenues from sales of DUEXIS in late 2011 following the commercial launch in the United States. LODOTRA is approved for marketing in over 35 countries outside the United States, and to date we have generated only limited revenues from sales of LODOTRA. RAYOS was approved by the FDA on July 26, 2012, and we began marketing it in the United States through our full field sales force in late January 2013. Following our November 2013 acquisition of the U.S. rights to VIMOVO, we began commercialization efforts in the United States in the first quarter of 2014. ACTIMMUNE was originally launched in the U.S. market in March 1991 by Genentech and in June 2012, Vidara acquired the intellectual property rights and certain assets related to the ACTIMMUNE product line. In September 2014, the businesses of Horizon Pharma, Inc. and Vidara were combined, and as a result we assumed the commercialization of ACTIMMUNE. In October 2014 we acquired the U.S. rights to PENNSAID 2% and expect to begin commercializing PENNSAID 2% in the United States in January 2015. We may never be able to successfully commercialize DUEXIS, VIMOVO, ACTIMMUNE, RAYOS or PENNSAID 2% or develop or commercialize other products in the United States, which we believe represents our most significant commercial opportunity. Our ability to generate future revenues depends heavily on our success in:

commercializing our existing products and any other product candidates for which we obtain approval; and

**Table of Contents**

FDA approvals for additional indications for ACTIMMUNE; and

securing additional foreign regulatory approvals for LODOTRA and DUEXIS; and

developing, acquiring or in-licensing and commercializing a portfolio of other product candidates in addition to DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA and PENNSAID 2%.

Even if we do generate additional product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our ordinary shares and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

*We may need to obtain additional financing to successfully commercialize or further develop our existing products, or to develop, acquire or in-license other products.\**

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

commercialize our existing products in the United States, including due to the substantial expansion of our sales force we completed in connection with our November 2013 acquisition of the U.S. rights to VIMOVO and the planned additional expansion of our sales force in connection with our acquisition of the U.S. rights to PENNSAID 2%;

complete the regulatory approval process, and any future required clinical development related thereto, for our products;

potentially acquire or in-license additional complementary products or products that augment our current product portfolio; and

conduct clinical trials with respect to ACTIMMUNE for other potential indications beyond GCD or SMO.

While we believe that our existing cash and cash equivalents at September 30, 2014 of \$248.8 million, together with interest thereon, and borrowings available under our credit facilities will be sufficient to fund our operations to the point of generating positive cash flow based on our current expectations of continued revenue growth, we may need to raise additional funds if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate, if we develop, acquire or in-license additional products or acquire companies, or if our revenues do not meet expectations.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives. We also could be required to:

seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or

relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

On June 17, 2014, we entered into a credit agreement with a group of lenders to provide us with \$300.0 million in financing through a five-year senior secured credit facility, or the Senior Secured Credit Facility. Funding of the Senior Secured Credit Facility occurred coincident with the closing of the merger with Vidara. While the credit agreement provides for an uncommitted accordion facility from which we may potentially finance future acquisitions, funding under the accordion facility is subject to the satisfaction of certain financial and other conditions that we

## Edgar Filing: Horizon Pharma plc - Form 10-Q

may not be able to meet at the times we may desire to fund an acquisition opportunity. If we are otherwise unable to secure financing to support future acquisitions, our ability to execute on a key aspect of our overall growth strategy would be impaired.

Our Swiss subsidiary, Horizon Pharma AG, is subject to Swiss laws regarding overindebtedness that require Horizon Pharma AG to maintain assets in excess of its liabilities. As of September 30, 2014, Horizon Pharma AG was not overindebted. However, Horizon Pharma AG has previously been overindebted, including at December 31, 2013. We will continue to monitor and review Horizon Pharma AG's financial position and, as necessary, will address any overindebtedness, which could require us to have cash at Horizon Pharma AG in excess of its near term operating needs and could affect our ability to have sufficient cash at our other subsidiaries to meet their near term operating needs.

Any of the above events could significantly harm our business, financial condition and prospects and cause the price of our ordinary shares to decline.



---

## **Table of Contents**

*Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish intellectual property rights to our product candidates.\**

We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our shareholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing shareholders' ownership. The incurrence of additional indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. For example, our borrowings under the Senior Secured Credit Facility subject us to significant fixed payment obligations in the future as we become obligated to repay the debt, and the Senior Secured Credit Facility contains affirmative and negative covenants that restrict our ability to incur additional indebtedness, grant liens, make investments, engage in mergers or dispositions, prepay other indebtedness and issue dividends or other distributions. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

*We generally have broad discretion in the use of our cash and may not use it effectively.\**

Our management has broad discretion in the application of our cash, and investors will be relying on the judgment of our management regarding the use of our cash. Our management may not apply our cash in ways that ultimately increase the value of any investment in our securities. We expect to use our existing cash to fund U.S. commercialization activities for DUEXIS, VIMOVO, ACTIMMUNE, RAYOS and, beginning in January 2015, PENNSAID 2%, to potentially fund additional regulatory approvals of DUEXIS, ACTIMMUNE and RAYOS/LODOTRA, to potentially fund development life cycle management or manufacturing activities of ACTIMMUNE, RAYOS/LODOTRA and PENNSAID 2% for other indications and for working capital, capital expenditures and general corporate purposes. We may also invest our cash in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our shareholders. If we do not invest or apply our cash in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our ordinary shares to decline.

*Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.\**

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. In September 2012, the sale of common stock and warrants to purchase ordinary shares in a public equity offering by Horizon Pharma, Inc. triggered an ownership change limitation and, as a result, we will be subject to annual limits on our ability to utilize net operating loss carryforwards of Horizon Pharma, Inc. We estimate that these annual limits will be a cumulative carryforward of \$49.9 million in 2014, and at a minimum, \$22.0 million for each of 2015 and 2016 assuming only the carryforward limitation. The net operating loss carryforward limitation is cumulative such that any use of the carryforwards below the limitation in one year will result in a corresponding increase in the limitation for the subsequent tax year.

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code limits the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, we expect this limitation is applicable following the Vidara merger. As a result, it is not currently expected that Horizon Pharma, Inc. or our other U.S. affiliates will be able to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable transactions following the Vidara merger. Notwithstanding this limitation, we expect that Horizon Pharma, Inc. will be able to fully utilize its U.S. net operating losses prior to their expiration. As a result of this limitation, however, it may take Horizon Pharma, Inc. longer to use its net operating losses. Moreover, contrary to these expectations, it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent Horizon Pharma, Inc. from fully utilizing its U.S. tax attributes prior to their expiration if Horizon Pharma, Inc. does not generate taxable income consistent with its expectations.

Any limitation on our ability to use our net operating loss carryforwards will likely increase the taxes we would otherwise pay in future years if we were not subject to such limitations.

*Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.\**



---

## Table of Contents

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. While there has been some recent improvement in some of these financial metrics, there can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate again, or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon commercialization or development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At September 30, 2014, we had \$248.8 million of cash and cash equivalents consisting of cash and money market funds. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since September 30, 2014, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us.

*Changes in accounting rules or policies may affect our financial position and results of operations.\**

U.S. generally accepted accounting principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations. In addition, our operation as an Irish company with multiple subsidiaries in different jurisdictions adds additional complexity to the application of U.S. generally accepted accounting principles and this complexity will be exacerbated further if we complete additional strategic transactions. Changes in the application of existing rules or guidance applicable to us or our wholly-owned subsidiaries could significantly affect our consolidated financial position and results of operations.

*Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.\**

In November 2013, Horizon Pharma, Inc. issued \$150.0 million aggregate principal amount of 5.00% Convertible Senior Notes due 2018, or the Convertible Senior Notes, to investors pursuant to note purchase agreements with such investors, and we subsequently guaranteed this debt at our parent entity. As of October 31, 2014, \$80.6 million of principal amount of the Convertible Senior Notes remained outstanding. We also substantially increased our overall indebtedness to finance the Vidara merger. On June 17, 2014, we entered into the Senior Secured Credit Facility and borrowed \$300.0 million, which is due after a five-year period. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Convertible Senior Notes and our borrowings under the Senior Secured Credit Facility, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

*Covenants imposed by the Senior Secured Credit Facility restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.\**

The Senior Secured Credit Facility provides for (i) a committed five-year \$300 million term loan facility, the proceeds of which were used primarily to effect the Vidara merger and pay fees and expenses in connection therewith and are being used in part for general corporate purposes; (ii) an uncommitted accordion facility subject to the satisfaction of certain financial and other conditions; and (iii) one or more uncommitted refinancing loan facilities with respect to loans under the Senior Secured Credit Facility. The Senior Secured Credit Facility imposes various covenants that limit our ability and/or our restricted subsidiaries' ability to, among other things:

incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;

issue redeemable preferred shares;

pay dividends or distributions or redeem or repurchase capital stock;

prepay, redeem or repurchase certain debt;

make loans, investments, acquisitions (including acquisitions of exclusive licenses) and capital expenditures;

enter into agreements that restrict distributions from our subsidiaries;

**Table of Contents**

sell assets and capital stock of our subsidiaries;

enter into certain transactions with affiliates; and

consolidate or merge with or into, or sell substantially all of our assets to, another person.

The covenants imposed by the Senior Secured Credit Facility and our obligations to service our outstanding debt:

limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;

limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;

may require us to use a substantial portion of our cash flow from operations to make debt service payments;

limit our flexibility to plan for, or react to, changes in our business and industry;

place us at a competitive disadvantage compared to our less leveraged competitors; and

increase our vulnerability to the impact of adverse economic and industry conditions.

If we are unable to successfully manage the limitations and decreased flexibility on our business due to our significant debt obligations, we may not be able to capitalize on strategic opportunities or grow our business to the extent we would be able to without these limitations.

Our failure to comply with any of the covenants could result in a default under the credit agreement, which could permit the administrative agent to, or permit the required lenders to cause the administrative agent to, declare all or part of any outstanding loans to be immediately due and payable or to exercise any remedies provided to the administrative agent, including proceeding against the collateral granted to secure our obligations under the Senior Secured Credit Facility. An event of default under the Senior Secured Credit Facility could also lead to an event of default under the terms of our Convertible Senior Notes. Any such event of default or any exercise of rights and remedies by our creditors could seriously harm our business.

*If intangible assets that we have recorded in connection with the Vidara merger become impaired, we could have to take significant charges against earnings.*

In connection with the accounting for the Vidara merger, we have recorded a significant amount of intangible assets. Under U.S. GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets has been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

**Risks Related to Our Intellectual Property**

*If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.\**

## Edgar Filing: Horizon Pharma plc - Form 10-Q

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the United States or in other foreign countries. If this were to occur, early generic competition could be expected against DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA, PENNSAID 2% and other product candidates in development. There is no assurance that the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the APIs in DUEXIS, VIMOVO and RAYOS/LODOTRA have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications.

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated.

---

**Table of Contents**

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. In March 2012, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Par for filing an ANDA against DUEXIS and seeking an injunction to prevent the approval of Par's ANDA and/or prevent Par from selling a generic version of DUEXIS. In January 2013, we filed a second suit against Par in the United States District Court for the District of Delaware claiming patent infringement of additional patents that have been issued for DUEXIS and seeking an injunction to prevent the approval of Par's ANDA and/or prevent Par from selling a generic version of DUEXIS.

On August 21, 2013, we entered into the Par settlement agreement and Par license agreement with Par relating to its patent infringement litigation. The Par settlement agreement provides for a full settlement and release by both us and Par of all claims that were or could have been asserted in the litigation and that arise out of the specific patent issues that were the subject of the litigation, including all resulting damages or other remedies.

Under the Par license agreement, we granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par's generic version of DUEXIS in the United States after the generic entry date and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par's generic version of DUEXIS prior to the generic entry date or the License. The License covers all patents owned or controlled by us during the term of the Par license agreement that would, absent the License, be infringed by the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States. Unless terminated sooner pursuant to the terms of the Par license agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the Par license agreement, the generic entry date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the License become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.

Under the Par license agreement, we also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by us during the term of the Par license agreement based on the manufacture, use, sale, offer for sale, or importation of Par's generic version of DUEXIS in the United States.

The Par license agreement may be terminated by us if Par commits a material breach of the agreement that is not cured or curable within 30 days after we provide notice of the breach. We may also terminate the Par license agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the Par license agreement will terminate automatically upon termination of the Par settlement agreement.

On July 15, 2013, we received a Paragraph IV Patent Certification from Watson advising that Watson had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. Watson has not advised us as to the timing or status of the FDA's review of its filing. On August 26, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against WLF seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that WLF has infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124, and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS containing 1 mg, 2 mg, and 5 mg of prednisone prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of WLF's ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid. We, together with Jagotec have granted WLF a covenant not to sue with respect to US Patent Nos. 6,677,326 and 8,168,218, respectively, and accordingly these patents have been dismissed from the lawsuit. The Markman claim construction hearing took place on October 16, 2014. The Court has not yet set a trial date for the WLF action.

On September 12, 2013, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. advising that Par Pharmaceutical, Inc. had filed an ANDA with the FDA for a generic version of RAYOS, containing up to 5 mg of prednisone. On October 22, 2013, we, together with Jagotec, filed suit in the United States District Court for the District of New Jersey against Par seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Par had infringed U.S. Patent Nos. 6,488,960, 6,677,326, 8,168,218, 8,309,124 and 8,394,407 by filing an ANDA seeking approval from the FDA to market generic versions of RAYOS prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book. On November 20, 2013, we were notified by counsel for Par that Par Pharmaceutical, Inc. had elected to withdraw its ANDA with the FDA for a generic version of RAYOS containing 2 mg and 5 mg of prednisone. On December 5, 2013, we entered into a Stipulation of Dismissal with Par Pharmaceutical, Inc. whereby Par Pharmaceutical, Inc. agreed to withdraw its application to market a generic version of RAYOS.





---

**Table of Contents**

Currently, patent litigation is pending in the District of New Jersey against four generic companies intending to market VIMOVO before the expiration of patents listed in the Orange Book. These cases are in the District of New Jersey and have been consolidated for discovery purposes. They are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy's; (ii) Lupin; (iii) Mylan; and (iv) Actavis. Patent litigation in the District of New Jersey against a fifth generic company, Anchen, was dismissed after Anchen recertified under Paragraph III. We understand that Dr. Reddy's has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium for the commercialization of VIMOVO, and that according to the settlement agreement, Dr. Reddy's is now able to commercialize VIMOVO under AstraZeneca's Nexium patent rights. The settlement agreement, however, has no effect on the Pozen VIMOVO patents, which are still the subject of patent litigations. As part of our acquisition of the U.S. rights to VIMOVO, we have taken over and are responsible for the patent litigations that include the Pozen patents licensed to us under the Pozen license agreement.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013 and October 23, 2013 and collectively include allegations of infringement of U.S. Patent Nos. 6,926,907 and 8,557,285. We understand the cases arise from Paragraph IV Notice Letters providing notice of the filing of an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the patents-in-suit. We understand the Dr. Reddy's notice letters were dated March 11, 2011 and November 20, 2012; the Lupin notice letter were dated June 10, 2011 and March 12, 2014; the Mylan notice letter was dated May 16, 2013; the Actavis notice letters were dated March 29, 2013 and November 5, 2013; and the Anchen notice letter was dated September 16, 2011. The court has issued a claims construction order and has set a pretrial schedule but has not yet set a trial date.

We intend to vigorously defend our intellectual property rights relating to DUEXIS, VIMOVO, ACTIMMUNE and RAYOS, but we cannot predict the outcome of the WLF matter related to RAYOS or the DRL cases, the Mylan cases, or the Watson cases related to VIMOVO. Any adverse outcome in these matters or any new generic challenges that may arise could result in one or more generic versions of DUEXIS, VIMOVO, ACTIMMUNE and/or RAYOS being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of DUEXIS, VIMOVO, ACTIMMUNE and/or RAYOS and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to DUEXIS, VIMOVO, ACTIMMUNE, RAYOS/LODOTRA or PENNSAID 2% fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them and threaten our ability to commercialize our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our products or any other product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

---

**Table of Contents**

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or U.S. PTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the U.S. PTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, the Patient Protection and Affordable Care Act allows applicants seeking approval of biosimilar or interchangeable versions of biological products such as ACTIMMUNE to initiate a process for challenging some or all of the patents covering the innovator biological product used as the reference product. This process is complicated and could result in the limitation or loss of certain patent rights. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States and Canada. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

*Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.*

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the U.S. PTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products and/or any other product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

## Table of Contents

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

*If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, we could lose license rights that are important to our business.\**

We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, we hold an exclusive license to SkyePharma AG's proprietary technology and know-how covering the delayed release of corticosteroids relating to RAYOS/LODOTRA. If we fail to comply with our obligations under our agreement with SkyePharma or our other license agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license, including RAYOS/LODOTRA.

In connection with our November 2013 acquisition of the U.S. rights to VIMOVO, we (i) received the benefit of a covenant not to sue under AstraZeneca's patent portfolio with respect to Nexium (which shall automatically become a license under such patent portfolio if and when AstraZeneca reacquires control of such patent portfolio from Merck Sharp & Dohme Corp. and certain of its affiliates), (ii) were assigned AstraZeneca's amended and restated collaboration and license agreement for the United States with Pozen under which AstraZeneca has in-licensed exclusive rights under certain of Pozen's patents with respect to VIMOVO, and (iii) acquired AstraZeneca's co-ownership rights with Pozen with respect to certain joint patents covering VIMOVO, all for the commercialization of VIMOVO in the United States. If we fail to comply with our obligations under our agreements with AstraZeneca or if we fail to comply with our obligations under our agreements with Pozen as we take over AstraZeneca's agreements with Pozen, our rights to commercialize VIMOVO in the United States may be adversely affected or terminated by AstraZeneca or Pozen.

We also license rights to patents, know-how and trademarks for ACTIMMUNE from Genentech, under an agreement that remains in effect for so long as we continue to commercialize and sell ACTIMMUNE. However, Genentech may terminate the agreement upon our material default, if not cured within a specified period of time. Genentech may also terminate the agreement in the event of our bankruptcy or insolvency. Upon such a termination of the agreement, all intellectual property rights conveyed to us under the agreement, including the rights to the ACTIMMUNE trademark, revert to Genentech. If we fail to comply with our obligations under this agreement, we could lose the ability to market and distribute ACTIMMUNE, which would have a material adverse effect on our business, financial condition or results of operations.

*We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.\**

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.



---

## **Table of Contents**

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares.

*Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.*

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

*We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.*

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

### **Risks Related to Ownership of our Ordinary Shares**

*We do not know whether an active, liquid and orderly trading market will develop for our ordinary shares or what the market price of our ordinary shares will be and as a result it may be difficult for you to sell your ordinary shares.\**

Although our ordinary shares are listed on The NASDAQ Global Market, an active trading market for our shares may never fully develop or be sustained even if it does. Further, an inactive market may impair our ability to raise capital by selling our ordinary shares and may impair our ability to enter into strategic partnerships or acquire companies or products by using our ordinary shares as consideration.

*The market price of our ordinary shares historically has been volatile and is likely to be highly volatile, and you could lose all or part of your investment.\**

The trading price of our ordinary shares has been highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this Risk Factors section and elsewhere in this report, these factors include:

our failure to successfully execute our commercialization strategy with respect to our approved products, particularly our commercialization of our products in the United States;

disputes or other developments relating to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products and product candidates;

unanticipated serious safety concerns related to the use of our products;

adverse regulatory decisions;

changes in laws or regulations applicable to our business, products or product candidates, including but not limited to clinical trial requirements for approvals or tax laws;

inability to comply with our debt covenants and to make payments as they become due;

inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;

**Table of Contents**

developments concerning our commercial partners, including but not limited to those with our sources of manufacturing supply;

our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

adverse results or delays in clinical trials;

our failure to successfully develop, acquire, and/or in-license additional product candidates or obtain approvals for additional indications for our existing product candidates;

introduction of new products or services offered by us or our competitors;

our inability to effectively manage our growth;

overall performance of the equity markets and general political and economic conditions;

failure to meet or exceed revenue and financial projections we may provide to the public;

actual or anticipated variations in quarterly operating results;

failure to meet or exceed the estimates and projections of the investment community;

publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

our inability to successfully enter new markets;

the termination of a collaboration or the inability to establish additional collaborations;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

our inability to maintain an adequate rate of growth;

ineffectiveness of our internal controls or our inability to otherwise comply with financial reporting requirements;

adverse U.S. and foreign tax exposure;

additions or departures of key management, commercial or regulatory personnel;

issuances of debt or equity securities;

significant lawsuits, including patent or shareholder litigation;

changes in the market valuations of similar companies;

sales of our ordinary shares by us or our shareholders in the future;

trading volume of our ordinary shares;

effects of natural or man-made catastrophic events or other business interruptions; and

other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The NASDAQ Global Market and the stocks of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may adversely affect the market price of our ordinary shares, regardless of our actual operating performance.

*We do not intend to pay dividends on our ordinary shares so any returns will be limited to the value of our shares.\**

We have never declared or paid any cash dividends on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future, including due to limitations imposed by the Senior Secured Credit Facility. Any return to shareholders will therefore be limited to the increase, if any, of our share price.

*Our officers, directors and funds affiliated with our directors own a significant percentage of our stock and will be able to influence matters subject to stockholder approval.\**



---

## **Table of Contents**

Our officers, directors and funds affiliated with our directors held in the aggregate approximately 8% of our outstanding voting ordinary shares as of September 30, 2014. Therefore, these shareholders have the ability to influence us through this ownership position, including through matters requiring stockholder approval. For example, these shareholders may be able to influence the elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction, such as the proposed merger with Vidara. This may discourage unsolicited acquisition proposals or offers for our ordinary shares that our shareholders may feel are in their best interest.

*We have incurred and will continue to incur significant increased costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives.\**

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In particular, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Stock Market, Inc., or NASDAQ, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. These rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time-consuming and costly. These effects will be exacerbated by our recent transition to an Irish company and the integration of Vidara's business and operations into the historical business and operating structure of Horizon Pharma, Inc. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will continue to decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain and maintain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. If we fail to comply with the continued listing requirements of NASDAQ, our ordinary shares could be delisted from The NASDAQ Global Market, which would adversely affect the liquidity of our ordinary shares and our ability to obtain future financing.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform annual system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our independent registered public accounting firm is also required to deliver a report on the effectiveness of our internal control over financial reporting. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts, particularly because of our Irish parent company structure and international operations. In particular, prior to the Vidara merger, Vidara and its affiliate entities were not subject to the requirements of the Sarbanes-Oxley Act. We intend to take appropriate measures to establish or implement an internal control environment at the former Vidara entities aimed at successfully adopting the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. However, it is possible that we may experience delays in implementing or be unable to implement the required internal controls over financial reporting and other disclosure controls and procedures. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, as well as retain and work with consultants with such knowledge. Moreover, if we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our ordinary shares could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC and by NASDAQ, would likely result in increased costs to us as we respond to their requirements.

*Sales of a substantial number of our ordinary shares in the public market could cause our share price to decline.\**

If our existing shareholders sell, or indicate an intention to sell, substantial amounts of our ordinary shares in the public market, the trading price of our ordinary shares could decline. In addition, our ordinary shares that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline.



---

**Table of Contents**

Certain holders of our ordinary shares are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. For example, we are subject to a registration rights agreement with certain holders of our ordinary shares prior to the Vidara merger. Pursuant to this agreement, we filed and are required to maintain a registration statement covering the resale of our ordinary shares held by these shareholders and in certain circumstances, these holders can require us to participate in an underwritten public offering of their ordinary shares. Any sales of securities by these shareholders or a public announcement of such sales could have a material adverse effect on the trading price of our ordinary shares.

*Future sales and issuances of our ordinary shares, securities convertible into our ordinary shares or rights to purchase ordinary shares or convertible securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to decline.\**

Additional capital may be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell ordinary shares, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell ordinary shares, convertible securities or other equity securities in subsequent transactions, our existing shareholders may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our ordinary shares. We also maintain equity incentive plans, including our 2014 Equity Incentive Plan, 2014 Non-Employee Equity Plan and 2014 Employee Share Purchase Plan, and intend to grant additional ordinary share awards under these and future plans, which will result in additional dilution to existing shareholders.

*Irish law differs from the laws in effect in the United States and may afford less protection to holders of our securities.\**

It may not be possible to enforce court judgments obtained in the United States against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised that the United States currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

As an Irish company, we are governed by the Irish Companies Acts, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the United States.

*Provisions of our articles of association could delay or prevent a takeover of us by a third party.\**

Our articles of association could delay, defer or prevent a third party from acquiring us, despite the possible benefit to our shareholders, or otherwise adversely affect the price of our ordinary shares. For example, our articles of association:

    permit our board of directors to issue one or more series of preferred shares with rights and preferences designated by our board;

    impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;

    stagger the terms of our board of directors into three classes; and

## Edgar Filing: Horizon Pharma plc - Form 10-Q

require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally in the election of directors for shareholders to amend or repeal our articles of association.

These provisions may discourage potential takeover attempts, discourage bids for our ordinary shares at a premium over the market price or adversely affect the market price of, and the voting and other rights of the holders of, our ordinary shares. These provisions could also discourage proxy contests and make it more difficult for you and other shareholders to elect directors other than the candidates nominated by our board.

---

## **Table of Contents**

*A transfer of our ordinary shares may be subject to Irish stamp duty.\**

In certain circumstances, the transfer of shares in an Irish incorporated company will be subject to Irish stamp duty, which is a legal obligation of the buyer. This duty is currently charged at the rate of 1.0% of the price paid or the market value of the shares acquired, if higher. Because our ordinary shares are traded on a recognized stock exchange in the United States, an exemption of this stamp duty is available to transfers by shareholders who hold our ordinary shares beneficially through brokers which in turn hold those shares through the Depositary Trust Company, or DTC, to holders who also hold through DTC. However, a transfer by a record holder who holds our ordinary shares directly in his, her or its own name could be subject to this stamp duty. We, in our absolute discretion and insofar as the Companies Acts or any other applicable law permit, may, or may provide that a subsidiary of ours will, pay Irish stamp duty arising on a transfer of our ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of our ordinary shares which would otherwise be payable by the transferee is paid by us or any of our subsidiaries on behalf of the transferee, then in those circumstances, we will, on our behalf or on behalf of our subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (iii) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or our subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares.

*If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.\**

The trading market for our ordinary shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our shares or publish inaccurate or unfavorable research about our business, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause our share price and trading volume to decline.

*We may become involved in securities class action litigation that could divert management's attention and harm our business and could subject us to significant liabilities.\**

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the equity securities of pharmaceutical companies. These broad market fluctuations may cause the market price of our ordinary shares to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Even if we are successful in defending against any such claims, litigation could result in substantial costs and may be a distraction to management, and may result in unfavorable results that could adversely impact our financial condition and prospects.

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

We completed the following issuances of unregistered securities during the nine months ended September 30, 2014:

In January 2014, we issued 20,711 ordinary shares to Parallax Biomedical Fund L.P. upon the cash exercise of a warrant and we received proceeds of \$89,222.99 representing the aggregate exercise price of such warrant.

In February 2014, we issued 20,711 ordinary shares to Cowen Overseas Investment L.P. upon the cash exercise of a warrant and we received proceeds of \$89,222.99 representing the aggregate exercise price of such warrant.

In March 2014, we issued 34,774 ordinary shares to Silicon Valley Bank upon the cashless exercise of warrants to purchase an aggregate of 41,631 ordinary shares.

In April 2014, we issued 242,857 ordinary shares to Deutsche Bank Securities, Inc. upon the cash exercise of a warrant and we received proceeds of \$1,109,856.49 representing the aggregate exercise price of such warrant.

## Edgar Filing: Horizon Pharma plc - Form 10-Q

In April 2014, we issued 607,143 ordinary shares to Alyeska Investment Group upon the cash exercise of a warrant and we received proceeds of \$2,774,643.51 representing the aggregate exercise price of such warrant.

In April 2014, we issued 285,714 ordinary shares to CD Ventures upon the cash exercise of a warrant and we received proceeds of \$1,305,712.98 representing the aggregate exercise price of such warrant.

In April 2014, we issued 48,325 ordinary shares to CBI GmbH upon the cash exercise of a warrant and we received proceeds of \$208,184.10 representing the aggregate exercise price of such warrant.

**Table of Contents**

In April 2014, we issued 48,325 ordinary shares to ANMA GmbH upon the cash exercise of a warrant and we received proceeds of \$208,184.10 representing the aggregate exercise price of such warrant.

In April 2014, we issued 38,602 ordinary shares to EkG Verwaltungs GmbH upon the cashless exercise of a warrant to purchase an aggregate of 55,229 ordinary shares.

In April 2014, we issued 276,147 ordinary shares to CD Ventures GmbH upon the cash exercise of a warrant and we received proceeds of \$1,189,641.28 representing the aggregate exercise price of such warrant.

In April 2014, we issued 260,351 ordinary shares to Fidelity upon the cashless exercise of a warrant to purchase an aggregate of 383,522 ordinary shares.

In May 2014, we issued 25,000 ordinary shares to Monashee Investment Management LLC upon the cash exercise of a warrant and we received proceeds of \$114,250 representing the aggregate exercise price of such warrant.

In May 2014, we issued 213,032 ordinary shares to Fidelity and its affiliates upon the cashless exercise of a warrant to purchase an aggregate of 342,566 ordinary shares.

In May 2014, we issued 220 ordinary shares to PHCV Grantor Trust upon the cashless exercise of a warrant to purchase an aggregate of 1,565 ordinary shares.

In June 2014, we issued 148,750 ordinary shares to Cranshire Capital Master Fund, LTD. upon the cash exercise of a warrant and we received proceeds of \$679,787.50 representing the aggregate exercise price of such warrant.

In June 2014, we issued 8,750 ordinary shares to Equitec Specialists upon the cash exercise of a warrant and we received proceeds of \$39,987.50 representing the aggregate exercise price of such warrant.

In June 2014, we issued 8,750 ordinary shares to Equitec Specialists upon the cash exercise of a warrant and we received proceeds of \$39,987.50 representing the aggregate exercise price of such warrant.

In July 2014, we issued 456,600 ordinary shares to OTA LLC upon the cash exercise of a warrant and we received proceeds of \$2,086,662.00 representing the aggregate exercise price of such warrant.

In August 2014, we issued 350 ordinary shares to Leonard Brabson upon the cash exercise of a warrant and we received proceeds of \$1,599.50 representing the aggregate exercise price of such warrant.

In September 2014, we issued 98 ordinary shares to Scale Venture Partners II, L.P. upon the cashless exercise of a warrant to purchase an aggregate of 62,166 ordinary shares.

## Edgar Filing: Horizon Pharma plc - Form 10-Q

In September 2014, we issued 96 ordinary shares to Essex Woodlands Health Venture Fund VII, LP upon the cashless exercise of a warrant to purchase an aggregate of 60,840 ordinary shares.

In September 2014, we issued 38 ordinary shares to Sutter Hill Ventures upon the cashless exercise of a warrant to purchase an aggregate of 24,347 ordinary shares.

In September 2014, we issued 1 ordinary share to Anvest, L.P. upon the cashless exercise of a warrant to purchase an aggregate of 872 ordinary shares.

In September 2014, we issued 2 ordinary shares to G. Leonard Baker, Jr. and Mary Anne Baker, Co-Trustees of the Baker Revocable Trust U/A/D 2/3/03 upon the cashless exercise of a warrant to purchase an aggregate of 1,272 ordinary shares.

In September 2014, we issued 1 ordinary share to Saunders Holdings, L.P. upon the cashless exercise of a warrant to purchase an aggregate of 958 ordinary shares.

In September 2014, we issued 3 ordinary shares to William H. Younger, Jr. Revocable Trust U/A/D 8/5/2009 upon the cashless exercise of a warrant to purchase an aggregate of 2,358 ordinary shares.

In September 2014, we issued 7 ordinary shares to Tench Coxe and Simone Otus Coxe, Co-Trustees of the Coxe Revocable Trust U/A/D 4/23/98 upon the cashless exercise of a warrant to purchase an aggregate of 4,935 ordinary shares.

In September 2014, we issued 2 ordinary shares to Jeffrey W. Bird and Christina R. Bird as Trustees of Jeffrey W. and Christina R. Bird Trust Agreement dated 10/31/00 upon the cashless exercise of a warrant to purchase an aggregate of 1,489 ordinary shares.



**Table of Contents**

On July 1, 2014, Horizon Pharma, Inc. repurchased 7,800 shares of its common stock from an employee at a price per share of \$15.79, representing the closing price of Horizon Pharma Inc.'s common stock on such date. The repurchase was the result of an arms-length private transaction at the employee's request in order to pay taxes upon vesting of restricted stock units. The following table provides information with respect to the repurchase:

<b>Period</b>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Value Paid by Company</b>
July 1, 2014 through July 31, 2014	7,800	\$ 15.79	\$ 123,171
August 1, 2014 through August 31, 2014	0	N/A	0
September 1, 2014 through September 30, 2014	0	N/A	0

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance on Rule 506 of Regulation D in that each issuance of securities was to an accredited investor under Rule 501 of Regulation D and did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

**Item 6. Exhibits**

The exhibits listed on the Index to Exhibits following the signature page are filed as part of this Quarterly Report on Form 10-Q.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**HORIZON PHARMA PLC**

Date: November 6, 2014

By: /s/ Timothy P. Walbert  
Timothy P. Walbert  
*Chairman, President and Chief Executive Officer*  
  
*(Principal Executive Officer)*

Date: November 6, 2014

By: /s/ Paul W. Hoelscher  
Paul W. Hoelscher  
*Executive Vice President and Chief Financial Officer*  
  
*(Principal Financial and Accounting Officer)*

**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
2.1(1)	Transaction Agreement and Plan of Merger, dated March 18, 2014, by and among Horizon Pharma, Inc., Vidara Therapeutics Holdings LLC, Vidara Therapeutics International Ltd. (now known as Horizon Pharma Public Limited Company), Hamilton Holdings (USA), Inc. and Hamilton Merger Sub, Inc.*
2.2(2)	First Amendment to Transaction Agreement and Plan of Merger, dated June 12, 2014, by and between Horizon Pharma, Inc. and Vidara Therapeutics Holdings LLC.
3.1(3)	Memorandum and Articles of Association of Horizon Pharma Public Limited Company.
4.1(4)	Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Comerica Bank.
4.2(4)	Warrant issued by Horizon Pharma, Inc. on December 18, 2007 to Hercules Technology Growth Capital, Inc.
4.3(4)	Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Comerica Bank.
4.4(4)	Warrant issued by Horizon Pharma, Inc. on November 21, 2008 to Hercules Technology Growth Capital, Inc.
4.5(5)	Form of Warrant issued by Horizon Pharma, Inc. pursuant to the Securities Purchase Agreement, dated February 28, 2012, by and among Horizon Pharma, Inc. and the Purchasers and Warrant Holders listed therein.
4.6(6)	Form of Warrant issued by Horizon Pharma, Inc. in Public Offering of Units.
4.7(7)	Indenture, dated as of November 22, 2013, by and between Horizon Pharma, Inc. and U.S. Bank National Association.
4.8(3)	First Supplemental Indenture, dated September 19, 2014, by and among Horizon Pharma, Inc., the Registrant and U.S Bank National Association.
4.9(7)	Form of 5.00% Convertible Senior Note due 2018.
4.10(3)	Registration Rights Agreement, dated as of September 1, 2014, by and among Vidara Therapeutics International plc (now known as Horizon Pharma Public Limited Company), Vidara Therapeutics Holdings LLC and certain shareholders of Vidara Therapeutics International plc.
10.1(3)	Form of Indemnification Agreement entered into by and between the Registrant and certain of its directors, officers and employees.
10.2(3)	Form of Indemnification Agreement entered into by and between Horizon Pharma, Inc. and certain directors, officers and employees of the Registrant.
10.3(3)	Temporary Escrow Agreement, dated September 19, 2014, by and among Vidara Therapeutics Holdings LLC, Horizon Pharma, Inc. and Citibank, National Association, as escrow agent.
10.4(3)	Horizon Pharma Public Limited Company Non-Employee Director Compensation Policy.
10.5(4)	2005 Stock Plan and Form of Stock Option Agreement thereunder.
10.6(8)	Horizon Pharma, Inc. 2011 Equity Incentive Plan, as amended, and Form of Option Agreement and Form of Stock Option Grant Notice thereunder.

---

**Table of Contents**

10.7(4)	Horizon Pharma, Inc. 2011 Employee Stock Purchase Plan and Form of Offering Document thereunder.
10.8(9)	Horizon Pharma Public Limited Company 2014 Equity Incentive Plan and Form of Option Agreement, Form of Stock Option Grant Notice, Form of Restricted Stock Unit Agreement and Form of Restricted Stock Unit Grant Notice thereunder.
10.9(9)	Horizon Pharma Public Limited Company 2014 Non-Employee Equity Plan and Form of Option Agreement, Form of Stock Option Grant Notice, Form of Restricted Stock Unit Agreement and Form of Restricted Stock Unit Grant Notice thereunder.
10.10(9)	Horizon Pharma Public Limited Company 2014 Employee Share Purchase Plan.
21.1	Subsidiaries of Horizon Pharma Public Limited Company.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

\* Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the Securities and Exchange Commission.

- (1) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on March 20, 2014.
- (2) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on June 18, 2014.
- (3) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed on September 19, 2014.
- (4) Incorporated by reference to Horizon Pharma, Inc. s Registration Statement on Form S-1 (No. 333-168504), as amended.
- (5) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on March 1, 2012.
- (6) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on September 20, 2012.
- (7) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on November 25, 2013.
- (8) Incorporated by reference to Horizon Pharma, Inc. s Current Report on Form 8-K, filed on March 4, 2014.
- (9) Incorporated by reference to the Registrant s Registration Statement on Form S-8 (No. 333-198865).